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Telephone: 01 406 1557 / 01 493 6401
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Aoife Garrigan, Contract Administrator, aoife.garrigan@ipu.ie
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The IPU Yearbook & Diary is the key information and reference publication for pharmacists, pharmaceutical companies, health professionals and health officials, as well as providing financial, insurance and other service supplier details.

The cost of the Yearbook is €60, including post and packing, with a 10% discount for 5 or more copies.

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Whatever your views on the concept of FMD, it is obvious that it is still a work in progress

With only two and a half years’ notice, Brexit seems to have caught the UK parliament by complete surprise. By amazing coincidence, after half a decade, FMD day has caught most of the pharma industry with their pencil sharpeners equally blunted.

In just a few days, most of Europe’s community pharmacists are supposed to turn on their scanners, merrily waiting for green lights. In this happy-clappy EC-inspired traffic light world, we are going to reject medicines that scan as red. I have been part of the trial. So far, about 80% – 90% of the drugs I scan come up red. Technically, this means that they are unfit to dispense and must be destroyed. Get real. This is bokers. None of these medicines are counterfeit. Their details either have not been uploaded to the database, or they have been loaded incorrectly. They are the same packs that I have been dispensing without an issue. They are not falsified. In my mind, and many other minds, this situation must not be allowed to stand.

It is clear since the implementation of FMD started, as the programmers and the committees started getting involved, that there was not enough consultation with the end-users. As they started to add features, they started to make the solution worse than the problem. Mission creep was the order of the day, further straying from the key issue, to prevent fake medicines entering the traditional and utterly regulated supply chain. When I scan a drug, I need to know only two things. Is it fake, or has it been dispensed previously? I do not care that some clerk in Slovenia accidently uploaded the wrong spreadsheet, nor do I give a whit if the batch number is inconsistent because of a data error. These are not fake medicines. As Brexit looms, with disruption being the order of the day, are we going to be expected to destroy essential medicines? Medicines that were genuine the day before? Medicines that, because some programmer, committee or robot couldn’t get its act together, were safe to dispense on the 8 February but are supposedly a critical hazard on the 9 February?

Whatever your views on the concept of FMD, it is obvious that it is still a work in progress. As I write, with weeks to go, there are only a few ‘on-boarding partners’ with working software. This shambles is utterly unacceptable. Hopefully, some sense will have arrived by the time you read this.

Speaking of notice, it is with a huge sense of sympathy that I see the correspondence from the current crop of 4th year pharmacy students. They seem to have suddenly realised the, in my view, iniquitous situation that they are in, compared with their predecessors. As we all know, this year sees the final group of paid internship students, previously known as pre-reg. They were paid a modest stipend, in recognition that the student was not only learning, but was contributing meaningfully to the workplace. This is complicated. I know that when the PSI held their targeted consultation on the Integrated Master’s pharmacy course, many pharmacists had reservations. Perhaps the most obvious one was “Why? What was the driver for change?”

Although the oft-quoted PEARS report gave comfort to those who wanted a makeover, it is unclear as to the brief that led to that voluminous tome. While the academics have their standards, there was a pervasive feeling at the time that this was merely a vanity project. While I am sure that this was, and is, untrue, it created a tone.

Many of the reservations arose from the removal of the final practical block year and its disassembly into four-month and eight-month portions. The implications of this restructuring were uncompromising. The first was for tutor pharmacists. Suddenly, the tutor business model failed. Heretofore, you could depend on having a student for a full year, acting as a valuable staff member. While it may not seem much, the lack of continuity presented a real practical issue. Given the antipathy from tutors, it seemed important that something had to give. The sweetener was that the student would no longer be paid. They would be pure students, with student hours and student responsibilities. Another nail in the coffin was that the final year would be a fully formed Master’s year, rather than a bolt on.

This requires full fees, as the HEA does not fund these. The net effect was that final year students were, typically, looking at a financial reversal in the order of €30,000, this being the difference between the lost earnings and the fee for a Masters. This, on the face of it, is unfair. However, you could look at the other side. Experienced pharmacists are giving time and resources to training students. It takes considerable effort to do this well. Perhaps, like in the UK, it is the experienced pharmacists that should be getting paid.
**Pharmacy in the Media**

In December, we issued a press release to highlight that medicine supply must be a top Government priority should there be a no-deal Brexit scenario. There was significant national media on the topic including items in *The Irish Times, Sunday Times, The Times, Irish Independent* and on RTÉ.ie. Darragh O’Loughlin was interviewed on RTÉ Radio 1. There was also extensive coverage across regional radio stations.

We issued a press release at the end of the month to advise that for help keeping your New Year’s Resolutions, visit your pharmacy for advice.

We also issued a press release in January to urge all people in at-risk groups for the flu to get vaccinated if they have not done so already as the peak flu season approaches. There was national coverage in *The Irish Times, Irish Daily Mail, Irish Daily Mirror* and on Newstalk.com, as well as coverage on RTÉ 2FM. There was also coverage in the *Tuam Herald*.

We were quoted in the *Irish Independent, Irish Examiner* and *Irish Daily Mail*, and online on BreakingNews.ie and Extra.ie in relation to reports on supply of medicines and Brexit.

Darragh O’Loughlin also appeared on *Claire Byrne Live* to discuss the topic.

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**Dates for your Diary**

**FEBRUARY 2019**

- **4 February** World Cancer Day, [www.worldcancerday.org](http://www.worldcancerday.org)
- **7 February** The 15th National Health Summit, [www.healthsummit.ie](http://www.healthsummit.ie)
- **7 February** Operation Transformation Weigh Your Age campaign
- **11 February** International Epilepsy Day, [www.internationalepilepsyday.org](http://www.internationalepilepsyday.org)
- **11 February** IPU Academy Spring Programme starts, [www.ipuacademy.ie](http://www.ipuacademy.ie)

**MARCH 2019**

- **10 – 16 March** World Glaucoma Week, [www.worldglaucomaweek.org/t](http://www.worldglaucomaweek.org/t)
- **11 – 17 March** National Brain Awareness Week, [www.nai.ie/go/brain_awareness_week](http://www.nai.ie/go/brain_awareness_week)
- **24 March** World TB Day, [www.stoptb.org](http://www.stoptb.org)
- **29 March** Early Bird Deadline for IPU conference, [www.pharmacyconference.ie](http://www.pharmacyconference.ie)
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IPU NEWS

IPU Academy Spring Programme – Book your courses online

The IPU Academy Spring Programme starts this month on Monday 11 February, with five interesting and current topics at venues nationwide. Courses are booking up fast. If you haven’t already booked, you can do so online at www.ipuacademy.ie.

You can view the IPU Academy Spring Programme and book your sessions in 3 easy steps:
1. Log on to www.ipuacademy.ie.
2. Enter your log-in details.
3. Book your courses.

The topics that will be covered during this programme are:
1. Introduction to Infertility;
2. Skin Health: Sun Protection;
3. Parkinson’s Disease;
4. Insulin Pump Therapy in Children (Express Topic); and
5. Type 2 Diabetes – Diet and Lifestyle Treatment, Education courses, Services & Supports (Express Topic).

If you have any queries in relation to IPU Academy, please email ipuacademy@ipu.ie.

Meeting with Department of Health

We had a meeting with the Department of Health in December, at which we discussed pharmacists’ role in the Government’s healthcare strategy, in particular IPU proposals for proven services that should be implemented under the Sláintecare plan, including:

- Minor Ailment Scheme to free up GP capacity;
- Prescription-free access to contraception to reduce barriers and improve uptake;
- NMS and MURs to improving patient care and health outcomes; and
- Reimbursement for Vaccinations and Emergency Medicines.

We also raised the need to commence the unwinding of FEMPI – we strongly emphasised our increasing frustration at the ongoing failure to define a clear exit pathway from FEMPI and to start the process of unwinding the cuts. The Department said that there would be a process of engagement over the course of 2019 in relation to the exit from FEMPI but that no details have been decided at this stage.

Lastly, there was a discussion on health service reform and the IPU’s collaboration on eHealth and cooperation with the PCRS, which cannot be taken for granted in the absence of reciprocation from the Department of Health and the HSE, and the need for a new fit for purpose Pharmacy Contract.

At the end of the meeting, it was agreed that there would be a further meeting with the Minister to follow up on the items raised, in particular, funded service proposals and the exit from FEMPI.

Company profiles are on www.ipu.ie

Our company profiles are now available online at www.ipu.ie > Communications > Company Profiles. If you are looking for information or contact details about a particular company, look no further than the IPU website. Last year, we moved the company profiles from the IPU Yearbook & Diary to the website, a move which provides additional opportunities for advertisers and allows the Company Profile section to be more accessible and user-friendly.

The list of profiles is sorted alphabetically but you have the option to sort them by business type. Users are also able to search by company name using the search bar at the top of the screen.
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- **Valganciclovir**
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- **Mycophenolate Mofetil Accord**
  - 250 mg x 100 Capsules
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#### HIV-1 INFECTION AND HEPATITIS B INFECTION
- **Tenofovir disoproxil**
  - 245 mg x 30 Film Coated Tablets

#### HEPATITIS B INFECTION
- **Entecavir (Actavis)**
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- **Pelgraz▼**
  - Pegfilgrastim
  - 6 mg Solution for Injection in Pre-Filled Syringe x 1

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  - 300 mg x 60 Film Coated Tablets
  - 500 mg x 120 Film Coated Tablets
- **Imatinib Accord**
  - 100 mg x 60 Film Coated Tablets
  - 400 mg x 30 Film Coated Tablets

#### HIV-1 INFECTION AND HEPATITIS B INFECTION
- **Tenofovir disoproxil**
  - 245 mg x 30 Film Coated Tablets

#### ANTI-VIRAL AGENT
- **Valganciclovir**
  - 450 mg x 60 Film Coated Tablets

#### IMMUNOSUPPRESSANT
- **Mycophenolate Mofetil Accord**
  - 250 mg x 100 Capsules
  - 500 mg x 50 Film Coated Tablets

#### HIV-1 INFECTION AND HEPATITIS B INFECTION
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Further information is available on request from Accord Healthcare Ireland Ltd, Euro House | Euro Business Park | Little Island | Cork | T43 K857 | Ireland. Tel: 021-461 9040 or from the SmPC available on www.accord-healthcare.ie

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Date of Preparation: September 2018 UK&IE/HIT/0002/10-17a
Pharmacists advise patients that it is not too late to get vaccine

On 10 January, we issued a press release to urge all people in at-risk groups for the flu to get vaccinated if they have not done so already. Those in at-risk groups include people aged 65 and over, pregnant women and people with chronic illness. Healthcare workers should also get the vaccine to protect themselves and those that they care for.

Ann Marie Horan, IPU Executive Committee member, explained the importance of getting the flu vaccine, “The flu is a highly-infectious and potentially a very serious illness. In recent years, January has been the peak month for flu cases including hospitalisations and unfortunately fatalities as well. The HSE says there has been a significant increase in flu cases reported at hospitals in recent days as schools reopen and people return to work. This year’s flu vaccine is a good match for circulating strains and the vaccine is the best way to protect yourself from getting the flu.

“While some people may feel that it is ‘too late’ in the flu season to avail of the vaccine, that is certainly not the case. The flu season in the Northern hemisphere typically runs until April, with January and February the most virulent time. For anyone who has not yet done so we would strongly recommend getting the flu vaccine at your earliest convenience, which you can get at your local community pharmacy.”

The vaccine is particularly important for those in at-risk groups. Ann Marie Horan advised, “Given the potentially serious complications of flu, anyone aged 65 years and over, pregnant women and those with a chronic illness should urgently avail of the flu vaccine. However, even those outside the at-risk groups should consider getting the vaccine, as by protecting themselves they are also protecting those around them.”

Member Benefits – Discounts on getaways with Logitravel

We have teamed up with Logitravel.ie, a leading online travel agency, to offer IPU members special discounted rates to a huge range of destinations. As an IPU member, you and your family/friends can now book and create your own short-haul and long-distance holidays, combining them with a flight, a hotel and a transfer, as well as booking multiple destinations. Logitravel has a huge range of destinations in Ireland, Europe and all over the world, at amazing prices. And that’s not all – as an IPU member, you get a discount of up to 10% on all holidays at all times, as well as seasonal and exclusive promotions. You can pay in one go or in instalments and thus spread the cost of your holidays. As an opening extra bonus, Logitravel has increased the discount for the first four weeks, so don’t delay, book today.

Visit https://ipu.bylogitravel.ie/ to get your exclusive IPU discount.

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IPU NATIONAL PHARMACY CONFERENCE

10 – 12 May 2019
The Galmont Hotel, Galway

pharmacyconference.ie
Community Pharmacy: Maximising Our Potential

The IPU National Pharmacy Conference is being held on 10 – 12 May in the Galmont Hotel (formerly the Radisson), Galway city. The three-day event provides support to the profession through an extensive programme of events, from clinical and business educational sessions to the Plenary Session to the return of the Panel Discussion.

We will be holding the Plenary Session, which proved extremely popular with last year’s attendees. This session will allow pharmacists and pharmacy stakeholders to recognise the necessity for the community pharmacy profession to develop a broader scope of practice in the future and be fully engaged in the wider health system. We will have three high-profile speakers present at the Plenary: Dr Ross T. Tsuyuki, Professor and Chair, Department of Pharmacology, Faculty of Medicine and Dentistry, University of Alberta; Margaret Wing, CEO, Alberta Pharmacists’ Association (RxA); and Terence A. Maguire, Pharmacist and Honorary Senior Lecturer, School of Pharmacy, Queen’s University Belfast.

We have taken on board suggestions from IPU members, through surveys and feedback, to organise a great line-up of sessions and speakers. We will have business and professional educational sessions delivered over the weekend.

Stamus Ruane, Galway-based contractor pharmacist with over 20 years’ experience in community pharmacy, will deliver 5 Ways to Increase Your Wellbeing at Work (No Matter How Busy You Are). This workshop will give you actionable, evidence-based steps to help you improve your wellbeing at work. The Pharmacist in an Atrial Fibrillation Clinic – A Model of Care is a session sponsored by one of our Gold Sponsors, Bristol Myers Squibb. During this informative session, you will gain a better understanding of atrial fibrillation, its diagnosis, complications and treatment. Eczema Diagnosis and Treatment: Tips and Tricks for the Community Pharmacist is a session sponsored by one of our Gold Sponsors, A Menarini. During this session, delivered by Dr Paul Ryan, the most recent prescribing guidelines on eczema are put into practice for the community pharmacist. We are looking forward to welcoming Jay Patel, Pharmacist and Executive Director, Day Lewis Plc, to speak on how you can Transform your Business using People, Process and Technology. Economist Jim Power, in association with Moore Wealth Management, will deliver on Economic Trends in 2019 and How they May Affect the Pharmacy Sector, which will consider the Irish economic environment in general, the behaviour of consumers, the public finances, Brexit, interest rates and how all of these issues impact on the pharmacy business. Jack Kavanagh, will deliver on Leading Through Adversity, which will reveal fundamental truths we can all relate to about the ebbs and flows of life, as Jack relays his personal story of adversity and his journey form surviving to thriving in life.

For information on all of these sessions visit www.pharmacyconference.ie/Programme.

Get the most out of your IPU membership and have your opinion count at the IPU AGM. The AGM is an opportunity for members to receive a confidential briefing on the latest issues affecting community pharmacists. The IPU President and the Secretary General will update members on the progress of the IPU over the last year and current issues affecting the profession. It is an important part of the conference as it is where all members can support the development of their profession and decide the next steps to take as the voice of community pharmacy, the AGM Motions help shape our focus over the coming year so make sure you are there to have your vote. The AGM will be held as one event this year, a similar format to last year, on the Sunday from 11.15am – 1.15pm.

As well as everything else the IPU conference has to offer, we will also have an Exhibition Hall, where over 30 companies will be available to meet with you and showcase their products and services. There will be plenty of opportunities to visit the Exhibition Hall on the Friday and Saturday of the conference, and investing time in the hall is a worthwhile opportunity to see what is available to meet with you and showcase their products and services. There will be plenty of opportunities to visit the Exhibition Hall on the Friday and Saturday of the conference, and investing time in the hall is a worthwhile opportunity to see what is available to meet with you and showcase their products and services. There will be plenty of opportunities to visit the Exhibition Hall on the Friday and Saturday of the conference, and investing time in the hall is a worthwhile opportunity to see what is available to meet with you and showcase their products and services.
We are delighted to welcome the return of the Panel Discussion; a conference event that we have not hosted since 2016.

The theme for the discussion will be Sláintecare – the Future Shape of Healthcare. During this session, we will discuss the Sláintecare Implementation Strategy and explore the potential role and contribution of pharmacists in delivering this strategy. Our exciting panel will include Laura Magahy, Executive Director at Sláintecare; Daragh Connolly, President of the IPU; Terence A. Maguire, Pharmacist and Honorary Senior Lecturer, School of Pharmacy, Queen’s University Belfast; and Aileen Bryson, Deputy Director and Practice and Policy Lead for the Royal Pharmaceutical Society (RPS) in Scotland.

Information about our Panel

Laura Magahy BA, MBA, Executive Director at Sláintecare
Laura Magahy has led some of Ireland’s most significant and transformational public-sector projects on behalf of Government, including the €1 billion urban renewal of Temple Bar and the Global Irish Forum initiative, Irish Design 2015. She has led change management and physical development projects in healthcare and has a particular interest in population-based planning and citizen engagement. Laura is a Fellow and past President of the Institute of Directors and is one of Ireland’s top Level A Project Directors. She is an honorary member of the Royal Institute of Architects in Ireland and has served on numerous public, private and plc boards as Chairman, Non-Executive Director and Executive Director.

Daragh Connolly, IPU President
Daragh Connolly was elected President of the IPU by the Executive Committee and took up the position at the IPU National Pharmacy Conference on 24 April 2016, and was re-elected for another term on 29 April 2018. He has been involved with the IPU for a number of years and was previously Vice-President. Daragh is a third generation pharmacist. He graduated from the University of Portsmouth in 1996, where he was President of the Pharmacy Students’ Association. He is a native of Waterford and proprietor of Haven Pharmacy Connolly’s in Dungarvan.

Aileen Bryson MRPharmS, Deputy Director, RPS
Currently Deputy Director and Practice and Policy Lead for the Royal Pharmaceutical Society (RPS) in Scotland, Aileen has had a varied career in many sectors of the profession. After pre-registration training in hospital, she became a community pharmacy owner for 17 years, before moving abroad where she had a short spell in industry and clinical trial work. On returning to the UK, she worked as a prescribing support pharmacist in England before relocating back to Scotland where she worked as an NHS 24 pharmacy advisor before joining the then regulator, RPSGB, as a policy lead. She subsequently was the primary care co-ordinator in NHS Lothian, before returning to policy in the new professional body, RPS.

Terence A. Maguire, Pharmacist and Honorary Senior Lecturer, School of Pharmacy, Queen’s University Belfast
Terence owns and runs two community pharmacies in Belfast and has authored three books and one book chapter, has co-authored articles published in journals, as well as presented at numerous conferences on subjects such as the future regulation of OTC nicotine products, obesity management in the pharmacy and pharmacy-based smoking cessation services. Terence will also present during the Plenary Session at the IPU conference.
The conference also offers invaluable networking opportunities and face-to-face contact with your colleagues.

There are numerous networking opportunities throughout the weekend, from the tea/coffee breaks in the Exhibition Hall, to the IPU President’s Dinner & Ball – a key social event in the pharmacy calendar. This year’s President’s Dinner & Ball takes place on Saturday 11 May as part of the conference weekend. You can book your dinner ticket at www.pharmacyconference.ie for just €35.

Pharmacy Staff

We are delighted to announce that pharmacy staff and technicians can attend the conference for the full weekend for just €60! This includes admission to all sessions and the Exhibition Hall, as well as Friday night dinner and daily refreshments and lunches (Saturday and Sunday).

Pharmacy staff are a key asset to your pharmacy business and the conference is the ideal place for them to attend educational courses. To support the continuing education of pharmacy technicians, we will also hold a CPD for Pharmacy Technicians session on the Sunday morning entitled Support and Care for Cancer Patients.

One in three people in Ireland are given a diagnosis of cancer. This is almost always a life-changing event which poses challenges for patients. Pharmacy staff can offer advice and support about medication and lifestyle measures to help improve patient outcomes. At the end of this course, pharmacy technicians will be able to discuss the appropriate use of anti-emetics and other ancillary treatments prescribed for patients receiving chemotherapy or radiotherapy; advise patients on how to maintain good general health and what to do if they feel unwell; and offer practical advice on skin care and general appearance to help patients to look good and feel better.

Conference Information and Registration

The conference is open to all pharmacists, non-pharmacist pharmacy owners who are IPU Members, pharmacy interns and all pharmacy staff who work for members of the IPU.

You can register online at www.pharmacyconference.ie/Registration. Please note, our Early Bird conference rate is available to IPU Members until 29 March 2019.

Your registration fee includes:

- Admission to all sessions;
- Entry to Exhibition Hall;
- Friday night dinner, with pre-dinner drinks;
- Daily refreshments and lunches (Saturday & Sunday); and
- Conference bag.

Cancellations & Refunds

Cancellations made prior to 19 April will be refunded in total. Refunds will not be processed after this date. Accommodation cancellations are at the discretion of the Galmont Hotel, Galway.

Condition of Entry

It is a condition of entry that you may be photographed at the event and that your image may be used on IPU and IPU National Pharmacy Conference material. The IPU reserves the right to refuse entry to anyone it sees fit.

Accommodation

The Galmont Hotel (formerly the Radisson) is located in Galway city, just a three-minute walk from the central Eyre Square and overlooking Galway Bay. It is also just a short walk from the main railway and bus stations. Use code IPU2019 when making your reservation for a special conference rate. The hotel can be booked by contacting them on 091 538 300.

To book your place at the 2019 IPU National Pharmacy Conference, please go to www.pharmacyconference.ie/Registration. The Early Bird rate for IPU Members is available until 29 March 2019. See you in Galway!
Census statistics show that there are currently 54,810 people with sight loss in Ireland – and this number is rising.

The National Council for the Blind Ireland (NCBI) is the national sight loss charity. We provide a wide range of services to people who are blind or vision-impaired in Ireland. You might be surprised to learn that 95% of the people who use our services have some useful vision and are not totally blind.

Our nationwide network of local support workers provides a range of practical and emotional services to people with sight loss. Our local support worker can talk to a person with sight loss and their family about their current situation, how sight loss is affecting their day-to-day life and what they would like to change, as well as their hopes and goals for the future. The impact of sight loss is explored at both a practical and an emotional level. We are here to help people to deal with their diagnosis and to talk to them about its impact on their life. Through our face-to-face counselling service, we can address issues such as fears the person may have if their sight is deteriorating, relationship difficulties and employment issues. We also provide a telephone counselling service, where the person can speak to a professional counsellor or a peer counsellor (someone who also has sight loss themselves) over the phone from the comfort of their own home.

A significant reduction in sight can make it difficult to continue reading and writing. Our local NCBI support worker will talk to the person about the difficulties they have with seeing to reading and writing, and discuss ways to make the most of the vision that they have. NCBI offers guidance and training in the use of a wide range of technology solutions. We can also assist the person with...
developing skills to help them get out and about, safely and independently.

Our employment service assists both the employee and the employer in enabling a person with sight loss to maintain employment or seek employment. With the onset of some eye conditions during employment, retention advice, awareness and reintegration can be offered. The service also provides advice on careers, third level education and training opportunities, job seeking and interview skills, as well as application procedures.

How to offer assistance to a person with sight loss

NCBI is committed to raising awareness of blindness and vision impairment. Here is a three-step approach to assisting a patient in your pharmacy who is blind or vision impaired.

The three-step approach

1. If you think someone needs help, walk up to them and say "hello";
2. Ask the person if they would like assistance. The person will accept your offer or tell you if they are ok; and
3. If the person needs help, ask them how you can help.

Do not assume the person needs help and do not assume what kind of help they need. Similarly, don’t assume that a person using a white cane or guide dog is totally blind. Many people with some remaining vision use these. Here are other ways you can help:

- If you know a person with sight loss, greet them by saying hello and your name, for example “Hello, it’s John here”;
- It’s easier if you know the person with sight loss by name – say their name when you are speaking to them. If you don’t know their name, don’t be afraid to ask, as well as giving your own name;
- Talk directly to the person rather than through a third party;
- If you’ve been talking to a person with sight loss, tell them when you are leaving, so that they are not left talking to themselves;
- In a group situation, introduce the other people present. Address the person with sight loss by name when directing conversation to them;
- If someone joins or leaves the group, tell the person with sight loss that this has happened;
- Don’t be afraid to use terms like “see you later” or “did you see”;
- If you are giving directions, don’t point. Give clear verbal directions, for example ‘the door is to your left’;
- Always let a person with sight loss know when you are approaching. A sudden voice at close range can be very startling. Speak first from a little distance away, and again as you get closer; and
- If you need to move something belonging to a person with sight loss, tell them what you have moved and where it is. If possible, put back the item to where it was so that they can find it later.

How to guide a person with sight loss

If a person with sight loss asks to be guided here is the best approach:

1. Make contact by touching the back of their hand with the back of your hand. Say, “take my arm”. Keep your arm by your side and the person with sight loss can walk a little behind you, holding your arm just above the elbow;
2. When you start walking you should be half a step ahead. Watch out for obstacles above, below and to the sides. It’s helpful to give commentary on what is around the person such as “there is a step down here”;
3. Walk at a pace that is comfortable for both of you and stop to explain obstacles if necessary;
4. Most importantly, relax.
How to make a referral to NCBI

If a patient tells you that they are having problems with their sight, the NCBI can help. A person with sight loss can avail of our services by filling out our online referral form at www.ncbi.ie or call us Monday to Friday, from 9.00am to 5.00pm on 01 830 7033.

When a person contacts us, we will request the person’s contact details and their eye condition, and any other additional information to gain a basic understanding of the person’s needs. This information is given to our local NCBI worker so that an appointment can be made to meet with the person in one of our local offices. During the first appointment, we will talk to the person further about any concerns or difficulties that they are having and find solutions together.

Sight Loss Awareness Days

NCBI will be participating in three awareness campaigns about sight loss this year. They are:

AMD Awareness Week
Each September, Novartis Ireland runs its annual AMD Awareness Week campaign. NCBI, along with the Association of Optometrists Ireland, Fighting Blindness and the Irish College of Ophthalmologists proudly collaborated with Novartis Ireland on the campaign. Find out more at www.amd.ie.

World Sight Day
This year, World Sight Day will be held on 10 October. We will again draw attention to issues surrounding the prevention of sight loss, so that no-one is needlessly losing their sight.

World Glaucoma Week
Another important advocacy event on the eye health calendar is World Glaucoma Day. This campaign will be held from 10 – 16 March 2019.

Keep an eye on our website, www.ncbi.ie, for more information about our campaigns.

You can also contact us on 01 830 7033, info@ncbi.ie, through our Facebook page, NCBI - Working for People with Sight Loss, or on Twitter @NCBI_sightloss.

Between 75% to 80% of blindness is preventable

Here are five easy tips to help protect your eyesight and those of your patients and prevent problems arising in the future.

1. Get an eye test
   Even though we might not need glasses, an eye test is a crucial health check for our eyes. The early symptoms of sight loss often go unnoticed and are usually not painful, so you may not realise you have a problem. Early detection is vital in the fight against sight loss – so visit your local optician to get an eye test.

2. Don’t smoke
   Smokers are more than twice as likely to experience sight loss in later life compared to non-smokers.

3. Eat healthy
   Eating fresh fruits and dark green leafy vegetables may delay, or reduce, the severity of eye conditions like age-related macular degeneration.

4. Keep fit
   Take regular exercise and monitor your blood pressure and cholesterol levels.

5. Wear 100% UV sunglasses
   UV radiation and sunlight can damage your eyesight all year round.

If you can’t follow all of our tips, make sure you do the most important thing; visit your optician and have an eye test.
Dear Editor,

New changes to pharmacy education in Ireland prohibit any payment to students resulting in financial and mental strain.

The new MPHARM degree, introduced in 2015, is a five-year integrated master’s programme run by the three Pharmacy Schools in Ireland; UCC, TCD and RCSI. As part of this new programme, pharmacy students must now complete a four-month placement in year four and an eight-month placement in year five, instead of a single 12-month placement block. Under the new rules, the Pharmaceutical Society of Ireland (PSI) insists students receive no wages during the required placements, irrespective of the employer’s wishes. This is due to the perception that a student-preceptor relationship is preferable to an employee-employer relationship. To a student on placement, these relationships are synonymous.

In addition to this, the fifth year fee has increased significantly from €3,000 for all colleges, to €7,500 in UCC, €8,500 in TCD and €9,000 in RCSI. As a result, each pharmacy student is looking at an approximate deficit of €25,000 over the course of their degree. The previous course structure allowed for pharmacy students to be paid by an employer for their internship year, but students are now faced with an increased financial burden without the same opportunity as previous students to earn during placement.

In addition to this, one third of pharmacy students are currently in receipt of the SUSI grant. It has recently been revealed that many students currently eligible for the grant will be ineligible during their final year, further worsening the situation for many. It is inevitable, and has even been suggested that some students will have to pause their studies and take a year out to fund the completion of their degree. Should this persist, the profession of pharmacy will be forced into one suited only to the affluent, rather than a profession open to all, with a vocation for patient-centred care.

Students are having to work up to seven days every week to support themselves financially and to be in a position to attend placement. A large proportion are working as paid technicians, performing near identical tasks to those which they complete on unpaid placements. In certain cases, a student will complete an unpaid day on placement, then begin a paid evening shift all within the same pharmacy. The cumulative effect of these changes is a significant strain on students and their families, both financially and mentally.

In order to safeguard the future profession of pharmacy, students are calling on the PSI to reverse this decision and allow payment for placement at the employer’s discretion. To this end, students from UCC, RCSI and TCD have united with the support of the Union of Students in Ireland (USI) to launch a campaign to allow a fair day’s wage for a fair day’s work.

The support to date from the profession has been extremely positive and should anyone wish to contribute, I would urge them to contact appelreps@gmail.com.

Yours,

Cian Crowe
UCC fourth year pharmacy student
Medicines authentication – a complete guide

Following the publication of the Delegated Regulation (EU) 2016/161 (the Regulation) under the Falsified Medicines Directive 2011/62/EU (FMD), there is a requirement on pharmacists to authenticate medicines during the dispensing process from 9 February 2019. The new EU law affects the entire pharmaceutical supply chain; this article examines how.

Effective 9 February, the EU Medicines Authentication Regulation is upon us. While pharmacy is at the cold face of the Regulation, it affects the whole supply chain in the EU, from manufacturing and import, right through to hand-over to the patient. This article sets out the work of stakeholders in Ireland to meet the new requirements.

First off, what is medicines authentication all about?

In 2011, the European Commission published legislation called the Falsified Medicines Directive, which aims to prevent counterfeit or falsified medicines getting into the supply chain. Guidelines were published by the Commission in February 2016 setting out exactly what manufacturers, wholesalers and pharmacists need to do to ensure that the medicines supplied to patients are authentic.

In summary, all EU pharma companies (originator companies, generic companies and parallel distributors) will put safety features, i.e. an anti-tampering device (tamper-evident seal) and a two-dimensional (2D) barcode, on each pack of medicine placed on the market. The 2D barcode contains a number which is unique to each and every individual product pack – see Figure 1.

You will start to see medicine packs come into your pharmacy with a 2D barcode and tamper-proof seal, and from 9 February 2019 you will be legally required to authenticate the medicine and mark it as supplied before you dispense to a patient.

EMVO

The European Medicines Verification Organisation (EMVO) was created as a joint initiative of EU stakeholders, representing manufacturers (Medicines for Europe, EFPIA, EAEPC), wholesalers (GIRP) and community pharmacists (PGEU) to deliver the European Medicines Verification System (EMVS) – the EU system at the centre of medicines authentication. The establishment of EMVO is mandated by EU law, specifically the FMD.

IMVO

Like EMVO, the establishment of the Irish Medicines Verification Organisation (IMVO) is mandated by EU law. Pharmaceutical manufacturers and marketing authorisation holders are obliged to set up, and fund, a not-for-profit legal entity to manage each national repository across the EU. In Ireland, IMVO is the relevant organisation. Its founder members include; the Association of Irish Pharmaceutical Parallel Distributors (AIPPD); the Irish Pharmaceutical Healthcare Association (IPHA); the Irish Pharmacy Union (IPU); Medicines for Ireland (generics industry); and the Pharmaceutical Distributors...
The Hospital Pharmacists’ Association of Ireland (HPAI) and BioPharmaChem Ireland (BPCI) have also been actively involved in the IMVO Steering Group since its inception in 2015, and the IMVO will continue to collaborate closely with both organisations.

The IMVO is working with the Health Products Regulatory Authority (HPRA) to ensure that the Irish national system meets the highest regulatory standards. Other important stakeholder organisations for the IMVO include, the Department of Health, the HSE and the European Medicines Verification Organisation (EMVO).

For the last number of years, Leonie Clarke MPSI has been the lead project manager for IMVO and is now the IMVO General Manager. Now that the IMVO is up and running, Leonie and her team are responsible for delivering the Irish Medicines Verification System (IMVS).

Manufacturers

While wholesalers and pharmacists connect to their national system, i.e. the IMVS, manufacturers and marketing authorisation holders (MAHs) connect to the European system, i.e. the EMVS.

Pinewood Healthcare

Pinewood Healthcare is a manufacturer of liquids, creams, ointments, and powders for the pharmaceutical and medical industries in Ireland and international markets. Discussing their preparation for 9 February, Jeffrey Walsh, Head of Sales with Pinewood, said, “Our preparations are highly advanced from both a manufacturing and wholesale point of view. Considerable expense has been outlaid to facilitate updating production lines, as well as utilising third party sources to implement the FMD. In relation to wholesaling, we will be decommissioning and verifying for some customers, so effectively these projects have required additional resources while at the same time minimising the effect on everyday business. We have installed new IT platforms and additional working capital has been deployed to secure extra stock to avoid and minimise the impact of stock outages as 9 February approaches. In parallel, we are working extremely hard with our contract manufacturers to make sure that all future stock, which has and will be confirmed for manufacture and scheduled to be delivered to Pinewood, will of course have tamper proof seals and 2D barcodes in order to be compliant with the FMD legislation.”

PCO Manufacturing

PCO Manufacturing is a parallel importer of pharmaceutical products into Ireland. Derek Colman, Consultant Project Manager for PCO Manufacturing, explains, “The Falsified Medicines Directive is arguably the largest and most complex project ever undertaken by the European Pharma Supply Chain and, for Parallel Distributors (PD), the complexity is even greater. As a repackaging facility, bound by the principles of Good Manufacturing Practice (GMP), we perform all of the FMD operations of a manufacturer (i.e. pack serialisation, tamper evidence and the upload of batch data to the European Hub). In addition, we must also capture and verify the safety features on each pack of medicine imported in order to facilitate our production process.

“In early 2016, PCO developed a comprehensive project plan in order to properly prepare for, and achieve, FMD compliance by the 9 February 2019 implementation date. The identification of production serialisation machinery, and the design and integration of appropriate software, was at the forefront of this plan. However, the development of the project has impacted on almost every department within the company through process changes.

“Another aspect is that PCO is both a manufacturer and a wholesaler which means that not only did we require software systems to enable connection to the European Hub (EMVO) but we also required a software system to connect to the Irish national database (IMVS). Easy FMD software has allowed us to do this seamlessly.
“PCO was one of the first MA holders to achieve a live connection to the EU Hub. On 30 May 2018, following two years of hard work and dedication by our superb multi-functional team, PCO very proudly became the first Irish MA holder to serialise and upload a batch onto the EU hub.

“While the uploading of our first batch to the EU Hub was certainly a significant milestone to celebrate, we very quickly realised that this was but a small step on the road to FMD compliance of our full portfolio of over 600 products. The process has been challenging and time-consuming, particularly in the following areas:

- We have had to amend the packaging of each one of those products through variations to the HPRA/EMA and packaging redesign. This follows through to the amendment of our repackaging processes for each of those products;
- We estimate that FMD will increase our average repackaging cost by 50%; and
- The challenge of the implementation of our new FMD machinery into our repackaging processes which are already quite automated.

“Now, as we return to work for the new year, we have an incredibly busy five weeks ahead of us as we approach D-Day of 9 February. We are confident, however, that our efforts will not be in vain. Our portfolio will be FMD compliant and we will be in a position to continue to provide our excellent service to our extensive and loyal customer base.”

AstraZeneca
Fintan McKearney, IS / IT Manager, explains the AstraZeneca approach and raises some concerns, “The AstraZeneca programme to comply with the EU FMD was kicked off in October 2015. Our capital investments within the broader Global Traceability Programme are in the range of over $200 million by 2020, which includes line upgrades and IT systems. The EU FMD programme alone includes review and changes of 2,300 SKU’s, 32 markets and 90 packaging lines. “Furthermore, 70+ professionals across all EU markets have been trained in preparation of GoLive, and further training and internal and external communication is planned for early 2019, including the creation of an external web page.

“Our primary concern short-term is that the number of alerts from pharmacies we may expect are extremely hard to predict, and could be very high in some countries. This may lead to an initial surge in alert investigations, which we predict could grow during the initial six months post-GoLive, as more serialised packs start to reach pharmacies. We are confident all our efforts will ensure the successful launch and implementation of the EU FMD.”

Wholesalers
In accordance with Article 23 of the Regulation, a wholesaler may verify and decommission medicinal products before it supplies that product to an institution other than a dispensing hospital or pharmacy, e.g. dispensing doctors.

United Drug Ireland (UDI) Cormac O’Callaghan, Head of Information Technology at United Drug Ireland (UDI), explains some of the technical and process implications of the Regulation, “UDI, as part of the McKesson Group, has been actively developing an integrated platform between our ERP (an IT system to manage core business processes) and warehouse systems to facilitate the identification of products, suppliers and customers within our warehouse environments to allow for:

- Verification of products where appropriate;
- Supply for our Article 23 customers; and
- Decommission of products where necessary.

“The changes implemented to our full line wholesale and pre-wholesale have been significant and have brought about new challenges with the extra handling required for the millions of medicinal packs that are managed and distributed to our customers. These challenges have been overcome with changes to our systems, infrastructure and our operational processes. “We recognise the significance of what will be delivered on 9 February, but we also recognise this is the start of a transition into our new supply chain, where serialisation becomes the standard and we are cognisant of the new challenges that may arise as the FMD processes are embedded and matured into our industry.

While there will be an impact on workflow, it is important to find a point in your pharmacy’s workflow that will minimise any disruption. Remember, the interface does not need to be part of your dispensary system or even on the same computer; it can be a fully standalone system giving you flexibility and options.”

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Perrigo Cold & Flu
To relieve all your Cold & Flu symptoms.

A choice you can feel better about

*Perrigo Cold & Flu Multi Relief Max Sachets*

**Paracetamol 1000 mg, Guaifenesin 200 mg, Phenylephrine 12.2 mg**

- For the relief of symptoms of colds and flu and the pain and congestion of sinusitis, including aches and pains, headache, blocked nose and sore throat.
- Clinically proven to provide relief from chesty coughs.
- Adults and children aged 12 years and over: 2 tablets every 4-6 hours when necessary to a maximum of 4 doses in 24 hours.
- Do not give to children under 12 years. Not to be used unless recommended by a doctor. Not to be continued for over 3 days without consulting a doctor.
- This product contains paracetamol which may be harmful to people with phenylketonuria.

**Contraindications**
- Hypersensitivity to any of the ingredients, hepatic or severe renal impairment, cardiovascular disorders, hyperthyroidism, diabetes, heart disease, those taking tricyclic antidepressants or beta-blockers, patients who are taking or have taken monoamine oxidase inhibitors within the last two weeks, those taking monoamine oxidase inhibitors for more than 14 days after stopping therapy with monoamine oxidase inhibitors, or those currently receiving other sympathomimetics, phaeochromocytoma, prostatic enlargement or urinary retention, closed angle glaucoma, and porphyria.

**Precautions**
- Not to be used during pregnancy or whilst breast feeding.
- Not to be taken in excess of the recommended dosage.
- Not to be combined with alcohol.
- Patients with hepatic or severe renal impairment, those taking tricyclic antidepressants or those currently receiving other sympathomimetics, phaeochromocytoma, prostatic enlargement or urinary retention, closed angle glaucoma, and porphyria should not take this medicine.

**Side Effects (unknown frequency)**
- Agranulocytosis, thrombocytopenia, abnormal hepatic function, hyperglycaemia, cutaneous hypersensitivity reactions, bronchospasm.

**Legal classification**
- P. PA 1120/1/2.

**Wrafton Laboratories Ltd. (T/A Perrigo), Braunton, Devon, EX33 2DL, UK. Date of preparation Apr 2018.**

**http://www.hpra.ie/img/uploaded/swedocuments/LicenseSPC_PA1120-001-001_06022018104036.pdf**

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**Perrigo Cold & Flu Multi Relief Capsules**

**Paracetamol 500 mg, Guaifenesin 200 mg**

- For the relief of symptoms of colds, flu and the pain and congestion of sinusitis, including aches and pains, headache, blocked nose, sore throat, lowering of temperature, and to loosen stubborn mucus, and to relieve chesty coughs.

**Contraindications**
- Hypersensitivity to any of the ingredients, hepatic or severe renal impairment, hyperthyroidism, diabetes, heart disease, those taking tricyclic antidepressants or beta-blockers, patients who are taking or have taken monoamine oxidase inhibitors within the last two weeks, those taking monoamine oxidase inhibitors for more than 14 days after stopping therapy with monoamine oxidase inhibitors, or those currently receiving other sympathomimetics, phaeochromocytoma, prostatic enlargement or urinary retention, closed angle glaucoma, and porphyria.

**Precautions**
- Not to be used during pregnancy or whilst breast feeding.
- Not to be taken in excess of the recommended dosage.
- Not to be combined with alcohol.
- Patients with hepatic or severe renal impairment, those taking tricyclic antidepressants or those currently receiving other sympathomimetics, phaeochromocytoma, prostatic enlargement or urinary retention, closed angle glaucoma, and porphyria should not take this medicine.

**Side Effects (unknown frequency)**
- Agranulocytosis, thrombocytopenia, abnormal hepatic function, hyperglycaemia, cutaneous hypersensitivity reactions, bronchospasm.

**Legal classification**
- P. PA 1891/3.

**Wrafton Laboratories Ltd. (T/A Perrigo), Braunton, Devon, EX33 2DL, UK. Date of preparation Apr 2018.**

**http://www.hpra.ie/img/uploaded/swedocuments/LicenseSPC_PA1120-001-003_14022018144055.pdf**

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**Perrigo Cold & Flu Multi Relief Powder for Oral Solution**

**Paracetamol 1000 mg, Guaifenesin 200 mg, Phenylephrine 12.2 mg**

- For the relief of symptoms of colds and flu and the pain and congestion of sinusitis, including aches and pains, headache, blocked nose and sore throat.
- Clinically proven to provide relief from chesty coughs.
- Adults, the elderly and children aged 12 years and over: One sachet every four hours as required to a maximum of 4 sachets (4 doses) in a 24-hour period.
- Do not give to children under 12 years. Not to be used unless recommended by a doctor. Not to be continued for over 3 days without consulting a doctor.
- This product contains paracetamol which may be harmful to people with phenylketonuria.

**Contraindications**
- Hypersensitivity to any of the ingredients, hepatic or severe renal impairment, cardiovascular disorders, hyperthyroidism, diabetes, heart disease, those taking tricyclic antidepressants or beta-blockers, patients who are taking or have taken monoamine oxidase inhibitors within the last two weeks, those taking monoamine oxidase inhibitors for more than 14 days after stopping therapy with monoamine oxidase inhibitors, or those currently receiving other sympathomimetics, phaeochromocytoma, prostatic enlargement or urinary retention, closed angle glaucoma, and porphyria.

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**Side Effects (unknown frequency)**
- Agranulocytosis, thrombocytopenia, abnormal hepatic function, hyperglycaemia, cutaneous hypersensitivity reactions, bronchospasm.

**Legal classification**
- P. PA 1120/1/3.

**Wrafton Laboratories Ltd. (T/A Perrigo), Braunton, Devon, EX33 2DL, UK. Date of preparation Apr 2018.**

**http://www.hpra.ie/img/uploaded/swedocuments/LicenseSPC_PA1120-001-005_27032018101342.pdf**
which can only happen with the continued collaboration between all parties involved in such a critical supply chain.”

**Community pharmacies**

To set your pharmacy up for medicines authentication, you will need:

- **Hardware** – a barcode reader; and
- **Software** – an interface into the Irish Medicines Verification System (IMVS).

The IPU provided all pharmacy members with a 2D barcode reader, supplied in November 2018 by a company called AIS Limited. If you have any questions about the scanner provided by the IPU, you can call AIS on 01 620 5742. There is also an IPU section on their website, www.aisltd.ie > Services > IPU.

**Scanning**

For all packs with a 2D barcode and a tamper-proof seal, you will check that the seal has not been broken and you will scan the 2D barcode. The software will then connect to the IMVS to authenticate the medicine and mark it as supplied. You will do this scanning at some stage during the dispensing process, at a point that suits the workflow in your pharmacy.

**Workflow**

Article 25 of the Regulation states that, “Persons authorised or entitled to supply medicinal products to the public shall verify the safety features and decommission the unique identifier of any medicinal product bearing the safety features they supply to the public at the time of supplying it to the public.” So, when exactly do you scan the medicine? This will vary from pharmacy to pharmacy, depending on what best suits the workflow of the pharmacy. It can be when preparing a prescription, or at handover to the patient. The most logical time to scan the medicine is when it is removed from the shelf before dispensing. We have inserted medicines authentication into the IPU template, Dispensing Process SOP, but you can move it to where it best reflects your workflow.

When the barcode is scanned, the number is checked in the IMVS to see if it is a valid serial number or if it is marked as previously dispensed, recalled or expired; the vast majority will be good to supply. The maximum response time of an individual repository is 300 milliseconds. If the system has to check repositories in other member states, e.g. for ULMs, each stage will take a maximum of 300 milliseconds. This means, the system is designed to be fast to have minimal effect on pharmacy workflow.

While there will be an impact on workflow, it is important to find a point in your pharmacy’s workflow that will minimise any disruption. Remember, the interface does not need to be part of your dispensary system or even on the same computer; it can be a fully standalone system giving you flexibility and options.

**Update your SOP**

The Regulation requires that you scan the medicine during the dispensing process, which starts when a prescription is received in the pharmacy, and continues until the medicine is supplied to the patient – you will need to amend your SOP for Dispensing Process accordingly, and there is an updated SOP on the IPU website; go to www.ipu.ie > Professional > SOPs and Guidelines > Dispensing Process.

**Support**

As set out in this article, there are a number of stakeholders involved in medicines authentication, so who do you go to for support? To simplify things, let’s break it down to the four core elements:

| Hardware | If you have trouble with the scanner, then contact the supplier, e.g. AIS. |
| Software | If you have trouble with the interface, then contact the interface provider. |
| Registration | If you have any issues registering with the national system, then contact IMVO. |
| Professional | If you have any questions about what to scan and when, contact the IPU. |

**IPU FAQ and Checklist**

For more information, read the IPU Medicines Authentication FAQ and Checklist on our website: www.ipu.ie > Professional > SOPs and Guidelines > Medicines Authentication.
Medisource is delighted to introduce our new online ordering system for exempt medicinal products. Pharmacists can register for online access at shop.medisource.ie

- Real-time stock information
- Easy search filter
- Tracking of online order history
- Fast re-order option
- Relevant product details e.g. HSE code, Fridge item, Foreign pack
- No fax requirement

The first dedicated and No. 1 supplier of unlicensed or difficult to get medicines in Ireland.

Medisource is Irish-owned and has a team of pharmacist-led experts to deal with your enquiries.
IPU Pilot to detect Hypertension and Atrial Fibrillation in the Community

High blood pressure is the leading cause of stroke and heart attack. High blood pressure is a silent killer that more than 1.2 million people in Ireland are set to have by 2020\(^1\).

Irish data on hypertension and atrial fibrillation suggests that the prevalence of each is rising with the growing elderly population. The data suggests that 64% of people over the age of 50 have high blood pressure, equivalent to 797,000 people in this age group, and nearly half of those are undiagnosed. Regarding atrial fibrillation, TILDA research suggests an overall Irish prevalence estimate of 3% atrial fibrillation in the over 50s; its prevalence is projected to at least double in the next 50 years as the population ages\(^2\). Whilst atrial fibrillation (AF) is not immediately life-threatening in the same way as some arrhythmias, it can lead to heart failure or stroke and so it has potentially serious effects. If undiagnosed, AF confers a 5-fold increase in risk of stroke, and one in five of all strokes is attributed to this arrhythmia. Ischaemic strokes in association with AF are often fatal and those patients who survive are left more disabled by their stroke and more likely to suffer a recurrence than patients with other causes of stroke. In consequence, the risk of death from AF-related stroke is doubled and the cost of care is increased 1.5-fold\(^3\).

The Cost of Stroke in Ireland study, carried out for the Irish Heart Foundation by the ESRI, estimated a total direct cost of stroke to the economy of up to €557 million per annum\(^4\). It is also estimated that stroke incidence will increase by
59% by 2030. As discussed previously, both hypertension and atrial fibrillation confer a high risk of stroke.

The need for prevention, early detection and comprehensive patient-centred management of chronic illnesses, including hypertension and atrial fibrillation, have been recognised by a number of Irish health system reports including the HSE report Living Well with a Chronic Condition: Framework for Self-Management Support, the PSI’s Future Pharmacy Practice in Ireland: Meeting Patients’ Needs and the Oireachtas Committee on the Future of Healthcare’s Sláintecare Report, which recommends the use of all available mechanisms and processes to ensure healthcare is delivered at the lowest level of complexity and is safe, efficient and good for patients. It also states that, “population health approaches can prevent chronic illness from developing in the first place, so prevention must be a strong focus of our health system”.

Pilot Aim and Outcomes

The aim of the IPU Pilot to Detect Hypertension and Atrial Fibrillation in the Community was to provide a health check and heart health information service to people 50 years of age and over, to determine the proportion of people in that cohort who may be at risk of hypertension and/or atrial fibrillation. A target was set to check 1,000 people during the pilot.

The proposed pilot outcomes were:

- Health check for people 50 years of age and over for hypertension and/or atrial fibrillation;
- Provision of heart health information to all participants;
- Referral of participant to GP where appropriate;
- Documentation of all health check outcomes and follow-up;
- Assessment of participant acceptability of the service; and
- Assessment of pharmacist acceptability of the service.

In order to ensure competence, conformity and uniformity across the pilot, in terms of health checks and information provided to patients, the Irish Heart Foundation was invited to work with the IPU on this pilot. The Irish Heart Foundation Standard Operating Procedures (SOPs) were used to ensure consistency in the health check. People who undertook the health check were offered lifestyle advice as appropriate and referred to their GP if considered necessary, using Irish Heart Foundation criteria.

Ethics approval and clinical trial registration

Ethics approval for the pilot was granted by the National University of Ireland (NUI).

Sinead McCool, Pilot Project Manager, Dr Declan O’Callaghan, Medical Director, Pfizer, Dr Angie Brown, Consultant Cardiologist and Medical Director, Irish Heart Foundation and Daragh Connolly, President of the Irish Pharmacy Union.
Galway Research and Ethics Committee. Dr Gerry Molloy from NUI Galway acted as an advisor in developing the methodology of the pilot. The pilot was registered as a clinical trial on the International Standard Registered Clinical/Social Study Number registry, ISRCTN with Study No: ISRCTN26825087.

**Study design**

Pharmacists who are members of the IPU were invited to take part in the pilot by letter and through the IPU’s weekly eNewsletter and monthly GM. Recruitment was undertaken as a clinical trial on the International Standard Registered Clinical/Social Study Number registry, ISRCTN with Study No: ISRCTN26825087.

Recruitment was undertaken in April and May 2018. All 105 pharmacists who expressed an interest in the pilot had to attend a mandatory training day, held in conjunction with the Irish Heart Foundation, on 5 July 2018. Each pharmacy was asked to recruit 20 people, with the aim of enrolling a total of 1,000 participants onto the pilot. The pilot ran from July 2018 to August 2018.

Participants who enrolled onto the pilot were provided with an information sheet on the pilot and asked to sign a consent form in advance of the health check taking place. All health checks were carried out in the pharmacy’s private consultation room. The pharmacist measured the person’s blood pressure, according to the Irish Heart Foundation SOP, and measured the person’s pulse, using the Kardia Mobile device. The pharmacist had the option of completing a manual pulse check, as per the Irish Heart Foundation SOP, if preferred. Each participant was given a written copy of their results. The IPU used their web-based platform, called IPUnet, to collect pilot data. Each participating pharmacist input all data collected from the consultation and survey into the IPUnet platform.

Depending on the results, people were offered lifestyle advice or counselling or a repeat health check as appropriate and referred to their GP if considered necessary, using Irish Heart Foundation referral criteria outlined in the SOPs.

People who were referred to the GP received a phone call from the pharmacy a few weeks later to ascertain if they had been diagnosed with hypertension or atrial fibrillation, prescribed a medicine or referred for further tests.

People who underwent the health check were asked to complete a survey with the pharmacist at the end of their health check to assess their acceptability of the service. The participant survey was also hosted on Survey Monkey so that the participant could be offered the option to complete the survey on their own.

Pharmacists were asked to complete an online survey at the end of the pilot to determine acceptability of the service, the reasons for success or lack of success and the feasibility within the service delivery environment.

**Results**

A total of 1,194 participants received a health check in 68 community pharmacies across Ireland over a two month period, which represents a check rate of approximately 16 patients nationally per day. The overall participant age range was from age 50 to age 96. Results show that:

- An irregular pulse (possible atrial fibrillation) was detected in 5.5% of participants who were checked;
- 27% of participants were identified with high blood pressure (possible hypertension);
- Both an irregular pulse (possible atrial fibrillation) and high blood pressure (possible hypertension) were noted in 2% of participants;
- 26% of all participants checked were referred to their GP; and
- 4% of the total population checked were commenced on medicines for hypertension, atrial fibrillation or both.

**Graph 1: Age Range (%) of Participants**

<table>
<thead>
<tr>
<th>Age Range</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>50-59 years</td>
<td>42</td>
</tr>
<tr>
<td>60-69 years</td>
<td>33</td>
</tr>
<tr>
<td>70-79 years</td>
<td>19</td>
</tr>
<tr>
<td>aged 80 and older</td>
<td>6</td>
</tr>
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The overall gender breakdown for pilot participants was 35% male and 65% female. In participants where hypertension was suspected, 44% were male and 56% were female. In patients where atrial fibrillation was suspected, the results were similar with 54% female and 46% male. These results suggest that, although more females undertook the health check, almost half of males checked were found to be at risk for either hypertension or atrial fibrillation.

**Hypertension**

In participants where hypertension was suspected, 79% of participants were referred to their GP. A review of follow up on participants who were referred to their GP found that 15% of this cohort had a new antihypertensive started; 1% had the dose of their current antihypertensive increased; 8% were found to have normal blood pressure readings on recheck at their GP; in 5% the GP was undertaking further monitoring; 3% were awaiting their GP appointment; non-adherence issues were identified in 2% of this group; a further 2% were referred on to a consultant; and 1% had a diagnosis of anxiety. 51% of participants in whom hypertension was suspected were lost to follow up.

Within this cohort of patients, 39% were currently prescribed antihypertensives, which could signal that there are issues around adherence or monitoring of blood pressure. This would correlate with the HSE’s Living Well with a Chronic Condition Framework, which acknowledged a high level of undetected hypertension, poor control of hypertension in Ireland, and the need to implement support for self-management of hypertension. The 2017 IPU New Medicine Service Pilot demonstrated that the pharmacist-led NMS intervention resulted in a positive effect on patient adherence, and the PSI Future Pharmacy Practice in Ireland: Meeting Patients’ Needs recommended that pharmacists should be integrated into building the capacity for patients’ self-care and self-management of chronic diseases including helping patients manage their medicines.

**Atrial fibrillation**

In participants where an irregular heart rate was suspected, 89% of participants were referred to their GP. Further follow-on participants showed that 15% of this group were then referred on to a consultant for further investigations, and 13% had a medicine started for the management of atrial fibrillation, with 1% having medicines for both atrial fibrillation and hypertension commenced. 10% of referrals were found to have a normal heart rate on re-testing at their GP; 3% were awaiting their GP appointment; 1% had a diagnosis of anxiety and 1% had a diagnosis of heart failure. 47% of this group were lost to follow up.

Of the participants referred to the GP with possible atrial fibrillation or hypertension, further follow up demonstrated that 7% had both an antihypertensive and anticoagulant commenced; 7% had an antihypertensive commenced and 7% were referred on to a consultant. In 28% of participants, the GP was monitoring the person. 14% of participants had not yet attended their GP and 35% were lost to follow up.
Participant feedback

There was a proactive element in participants seeking checks, with 20% alerted to the pilot via information on display in the pharmacy or social media, 10% took part as they were worried about their health in general, 14% as they were worried about their blood pressure and 7% as they were worried about their heart health. Participants appeared to have a reasonable knowledge of blood pressure and its detection and management, with 43% of participants aware of what their blood pressure reading was. The majority of participants were aware of what a normal blood pressure reading was (58%), and the problems high blood pressure could potentially cause (61%). However, in regards to knowledge of issues around pulse rate, only 25% of participants knew what atrial fibrillation was, 22% knew what their pulse rate was and only 20% knew of problems associated with an irregular pulse rate. This represents a large knowledge gap in those that were checked, as the figures suggest that only one in five checked had an awareness of the issues around pulse rate and pulse checks.

Overall, the information and support provided by pharmacists during the health check was rated very highly by participants, with 83% happy with the information they were given by the pharmacist who undertook the health check. Almost all participants (98.5%) would like their community pharmacist to be able to provide the blood pressure and pulse health check service to all people 50 years of age and older. This meets the SláinteCare’s principles of ensuring that healthcare is delivered at the lowest level of complexity and is safe, efficient and good for the patients, and that priority is given to health promotion and preventive care.

Pharmacist feedback

The benefits of the pilot training programme provided by the IPU and the Irish Heart Foundation can be seen in the pharmacist survey results, as almost all pharmacists who completed the survey (97%) felt they had been given sufficient training to provide the health check service and 85.5% of respondents rated the training as very good or excellent. The health check service also had a positive impact on pharmacists’ activities; in addition to the 42% who stated they already carried out other health check activities, others have decided to include the addition of pulse checks to the blood pressure checks the pharmacy already provided, and more are considering commencing health checks in their practice. 98% of pharmacists thought that this health check service should be rolled out as a HSE-remunerated service. Funding for health check services should allow for protected time to conduct the health check, educate and follow up on patients, whilst not compromising other activities in the community pharmacy.

Use of the Kardia® Mobile Device was a major success as 91% of pharmacists rated it as very good or excellent. Some pharmacists made the following comments in relation to the Kardia® Mobile Device:

- Since pilot has finished, I am still using the Kardia® device and sent a patient to hospital with possible AF. It is a great device to have as a further check on patients you might have concern about.
- The Kardia® gadget was great to use. Helped in particular with one young gentleman in eliminating MI. But GP very happy he was referred as was a torn muscle in sternum.
- We have added on a Kardia® check as part of all our BP screenings going forward.

Feedback from pharmacists concurred with the extremely positive feedback from participants:

- Feedback from patients was good from the outset.
- Patients were interested and grateful.

Pharmacist feedback also identified the role of the community pharmacist in identifying and managing the unmet needs of patients via this health check service.

- Resulted in referral of patients who otherwise would not have attended a GP
- Enabled early detection, which in the long run will save on extra health service costs further down the road.
- We, as pharmacists, have the ability to do this kind of screening which can identify conditions earlier, allowing GPs to manage these conditions and keep patients out of hospitals.
- It was a useful screening exercise and health promotion tool.

The SláinteCare Report recommended the use of all available mechanisms and processes to ensure healthcare is delivered at the lowest level of complexity and is safe, efficient and good for the patients, and that population health approaches can prevent chronic illness from developing in the first place, so prevention must be a strong focus of the Irish health system.

The IPU pilot demonstrated that, by carrying out a standardised population health check for hypertension and atrial fibrillation in the community pharmacy, a highly accessible healthcare location, community pharmacists can deliver an extremely positive benefit to participants in terms of prevention, detection and initial management of the conditions of hypertension and atrial fibrillation.

References

5. Health Service Executive. Living Well with a Chronic Condition – the National Framework and Implementation Plan for Self-management Support for Chronic Conditions: COPD, Asthma, Diabetes and Cardiovascular Disease 2017
9. www.alivecor.com Kardia Mobile Application Software ©2018 AliveCor Inc
Pharmacokinetics
Part Five – Excretion: Clinical Implications

In this final article, we will look at drug excretion and factors which affect this process, including drug interactions, variability due to ageing and disease. The article aims to highlight some of the key theoretical concepts of drug excretion, through the use of practical examples of where pharmacists can optimise patient care.

Drug excretion is the process by which drug is removed from the body, either as a metabolite or unchanged drug. Whilst there are many different routes of excretion including sweat, saliva, tears and milk, most drugs are either excreted in the bile or the urine. Volatile drugs such as alcohol and inhalational anaesthetics, are excreted via the lungs into expired air.

Renal excretion
The kidney is the principal organ involved in drug excretion. Renal excretion involves four processes (Figure 1). A knowledge of these processes is required in order to understand the factors which can affect renal excretion.

1. Glomerular filtration
Blood enters the kidneys along the afferent arteriole and is delivered to the glomerular capillaries, where some molecules are small enough to pass through the pores of the glomerular membrane into the Bowman’s capsule and tubular fluid.

2. Reabsorption
The renal tubular cells possess active and passive transport systems for the reabsorption of some drug molecules / metabolites from the tubular fluid, back into the blood.
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3. **Active secretion**  
For drugs which escape glomerular filtration, active transport systems are able to remove drugs/metabolites from blood in the peritubular capillaries and secrete them into the tubular fluid.

4. **Urinary excretion**  
Drugs and metabolites remaining in the tubular fluid are subsequently removed from the body in the urine.

Altered renal perfusion, interference with renal transport system activity and changes in renal tubular fluid pH can all have an impact on the excretion of drug from the body.

**Changes in renal perfusion**

Advancing age results in reduced renal blood flow and, consequently, a reduction in renal clearance. This results in reduced excretion of water-soluble drugs. This is of particular importance for drugs with a narrow therapeutic window such as digoxin and lithium. A lower maintenance dose of these drugs is usually required in older patients. It is also important to bear in mind that regular review of these types of medications is necessary. For example, a 250 microgram dose of digoxin may be an appropriate maintenance dose initially, but as the patient ages (and their renal function declines) this dose may no longer be suitable. The Summary of Product Characteristics (SPC) advises, “when dealing with an elderly patient, the dosage should be reduced and adjusted to the changed pharmacokinetics to prevent elevated serum dioxin levels and the risk of toxicity”. Acute illness can further amplify reduction in renal clearance in these patients, particularly if accompanied by dehydration (for example, if they develop vomiting, diarrhoea or infections associated with increased fluid loss).

Drugs are also known to induce changes in renal blood flow. Renal vasodilatory prostaglandins are involved in the control of renal perfusion. If the synthesis of these prostaglandins is reduced, renal excretion of some drugs may be compromised. A well-documented interaction of this type is with lithium and non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs can increase lithium levels leading to toxicity. However, Stockley’s Drug Interactions notes there is great variability between NSAIDs and also between individuals taking the same NSAID. NSAIDs should be avoided in patients taking lithium, particularly if other risk factors are present (e.g. older patient, concomitant use of nephrotoxic drugs), unless serum lithium levels can be very closely monitored (initially every few days) and the lithium dose reduced appropriately. Self-medication of NSAIDs (for example, over-the-counter) should be avoided for patients taking lithium, and a non-interacting alternative (such as paracetamol) used. Despite the interaction, some patients will be prescribed concomitant lithium and an NSAID. In this case, prescribers should be alerted to the interaction, whilst symptoms of lithium toxicity (e.g. gastro-intestinal disturbance, visual disturbance, polyuria, muscle weakness, tremor, and CNS disturbance) should be reinforced with patients, advising them to report these immediately should they occur.

**Changes in renal transport system activity**

Drugs using the same active transport systems in renal tubules can compete with each other for excretion. Aspirin reduces the renal clearance of methotrexate by competitively inhibiting the tubular secretion of methotrexate. In addition, aspirin inhibits the production of renal vasodilatory prostaglandins which reduces blood flow to the kidneys. This dual mechanism of interaction results in accumulation of methotrexate leading to an
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increased risk of toxicity. Penicillin antibiotics are another group of drugs which are capable of competing with methotrexate within the tubules of the kidney, leading to reduced tubular secretion and potential accumulation of methotrexate. Since the evidence for this mechanism is mostly limited to animal studies and human case reports, there is not enough evidence to contraindicate concurrent use. If concurrent use of methotrexate and a penicillin antibiotic is required, it is recommended that patients are carefully monitored during treatment for methotrexate toxicity.

**Changes in urinary pH**

It has been found that the serum salicylate levels of patients taking large anti-inflammatory doses of aspirin can be reduced to subtherapeutic levels by some antacids. This is explained by the fact that aspirin is an acidic compound excreted by the kidney tubules. Antacids can increase the pH of the tubular fluid, resulting in a more alkaline environment and consequently most of the aspirin exists in the ionised form. Ionised drug is not readily reabsorbed across the renal tubular cells and is therefore lost in the urine (Figure 2). It should be noted that Stockley’s Drug Interactions states that “no important adverse interaction would be expected in those taking occasional doses of aspirin for analgesia”. The clinical significance of this interaction mechanism is negligible, because although a very large number of drugs are either weak acids or bases, almost all are largely metabolised by the liver to inactive compounds and few are excreted in the urine unchanged. However, this type of interaction has been used to its advantage, where the deliberate manipulation of urinary pH (using sodium bicarbonate) has been used to increase the removal of drugs such as aspirin in cases of overdose.

**Renal impairment**

Whilst an in-depth discussion on renal impairment is beyond the scope of this article, it is worth noting that because most drugs or their metabolites are excreted by the kidney, that patients with renal impairment will require special consideration. Impaired renal function alters drug clearance, potentially changing drug efficacy and increasing the possibility of adverse effects, including renal toxicity. Patients with renal impairment, who are given drugs that are mainly renally excreted, will require the dose or dose frequency to be adjusted. Direct acting oral anticoagulants (DOACs) are an example of a drug group which can be misprescribed in this respect. All of the DOACs are renally excreted, so dose selection and modification may be necessary in patients with renal impairment to avoid both thromboembolic events and bleeding complications. Furthermore, some DOACs are contraindicated in severe renal impairment. Guidance for specific DOACs differ; however, comprehensive advice on regimen adjustment in renal impairment is available in the individual product’s SPCs. Other commonly prescribed drugs which require an altered regimen in renally impaired patients include allopurinol, lithium, aciclovir, gabapentin, metformin, digoxin, enoxaparin and aminoglycoside antibiotics. Further information can be found in product SPCs.

**Enterohepatic recirculation**

Whilst the renal route is the predominant mode of drug excretion, some drugs are excreted in the bile and faeces. Following their passage through the liver, drug molecules or their metabolites (conjugates) may be excreted into the bile. The bile is released into the gut lumen, from which the parent drug molecules may be reabsorbed. Additionally, enzymes produced by the intestinal bacterial (flora) can hydrolyse conjugated metabolites, freeing the active drug, which in turn may also be

“In anecdotal cases, the failure of oral combined hormonal contraceptives has been attributed to broad spectrum antibiotics such as penicillins and tetracyclines.”
reabsorbed. This cycle is called the ‘enterohepatic cycle’ and may be repeated several times, significantly prolonging the body exposure to the drug.

In anecdotal cases, the failure of oral combined hormonal contraceptives has been attributed to broad spectrum antibiotics such as penicillins and tetracyclines. It is established that ethinylestradiol undergoes enterohepatic recirculation, and one early hypothesis to explain contraceptive failure was that suppression of the intestinal flora (by the broad spectrum antibacterial) reduced the hydrolysis of the steroid conjugate, hence reducing enterohepatic recirculation and the woman’s exposure to ethinylestradiol. However, controlled studies have not shown any reduction in contraceptive exposure (and subsequent suppression of ovulation) in women given such antibacterial agents. Possible alternative explanations, which may explain contraceptive failure in this case, include vomiting and/or diarrhoea caused by the antibiotic or the illness being treated, or failure to take the contraceptive correctly due to the illness. Combined hormonal contraception is not 100% effective, even with perfect use and so it could be the case that some cases of contraceptive failure with antibacterials are simply coincidental, representing a chance association, rather than an interaction. Despite the limited evidence for this interaction, a cautious approach has traditionally been adopted, where it has generally been recommended that an additional contraceptive method should be used during the course of antibiotic and for seven days after finishing the course. Following review of all the available evidence, the UK Faculty of Sexual and Reproductive Healthcare in their current guidance on hormonal contraceptives state that additional contraceptive precautions are not required during the use of antibiotics (non-enzyme inducing) unless the medication and/or the illness cause vomiting or diarrhoea (as this will affect the absorption of the active ingredients). From an evidence-based point of view, this approach is the one most readily justified, although individual product SPCs should also be consulted.

Summary

Drug excretion is the process by which drug is removed from the body, either as a metabolite or unchanged drug. The process is highly influenced by a number of factors, including drug interactions, disease and the ageing process. Clinical outcomes of such variables can be significant for the patient and can result in toxicity or sub-therapeutic effects. Pharmacists are ideally placed to identify and manage these factors (such as drug interactions) which will impact on patient care and outcomes.

Further references available on request.

Your 5-minute assessment

Answer the following five questions true or false:

1. The kidney is the principal organ involved in drug excretion.
   - True

2. Digoxin is primarily excreted by the renal route.
   - True

3. Self-medication of NSAIDs can lead to sub-therapeutic levels of lithium due to altered excretion.
   - False. NSAIDs can increase lithium levels leading to toxicity.

4. DOACs, such as dabigatran, are renally excreted, so dose selection and modification may be necessary in patients with renal impairment.
   - True. DOACs, such as dabigatran, are renally excreted, so dose selection and modification may be necessary in patients with renal impairment.

5. The UK Faculty of Sexual and Reproductive Healthcare in their current guidance on hormonal contraceptives states that additional contraceptive precautions should be used whilst taking broad spectrum antibiotics, such as amoxicillin, and for seven days after the course.
   - False. The UK Faculty of Sexual and Reproductive Healthcare in their current guidance on hormonal contraceptives states that additional contraceptive precautions should be used whilst taking broad spectrum antibiotics, such as amoxicillin, and for seven days after the course.

Please note, this is Part Five of the series on Pharmacokinetics. Part One of the series was published in May 2018, Part Two of the series was published in August 2018, Part Three of the series was published in October 2018 and Part Four of the series was published in November 2018.
Self-appraisal

☐ Do I understand the term drug excretion?
☐ Am I familiar with the clinical relevance of drug excretion, including interactions which affect this process?
☐ Can I apply and integrate knowledge gained to my daily practice?
☐ Can I counsel patients effectively in terms of management of interactions affecting drug excretion?
☐ Am I aware of how ageing can affect the excretion of various drugs?
☐ Can I advise prescribers effectively in terms of management of interactions affecting drug excretion?
☐ Am I familiar with how disease states can impact on drug excretion and clinical consequences of this?

Personal plan

Including a list of desired learning outcomes in a personal learning plan is a helpful self-analytical tool.

☐ Create a list of desired learning outcomes.
☐ How will I accomplish these learning outcomes?
☐ Consider how to identify and manage drug interactions which may interfere with the excretion process.
☐ Identify resources available to achieve learning objectives.
☐ Develop a realistic timeframe for the plan.

Action

Activities chosen should be outcomes based to meet learning objectives.

☐ Implement plan.
☐ Read this article on Pharmacokinetics – Excretion: Clinical Implications
☐ Evaluate professional resource materials available in the pharmacy and source additional material if necessary.

Evaluate

Consider outcomes of learning and impact of learning.

☐ Have I met my desired learning outcomes?
☐ Do I now feel confident to engage with prescribers on how to manage drug interactions affecting the drug excretion process?
☐ Do I now feel confident to counsel patients on how to manage drug interactions affecting the drug excretion process?
☐ Provide example(s) of changes I have implemented in my pharmacy practice.
☐ Have further learning needs been identified?

Document your learning

☐ Create a record in my ePortfolio.
☐ As part of this record, complete an evaluation, noting whether learning outcomes were achieved and identifying any future learning needs.
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At the time of going to print, the process of ratifying the Withdrawal Agreement and Political Declaration continued at Westminster, and the Irish Government continued its no-deal Brexit contingency planning. Four Memos were brought to Government on legislation required in a no-deal scenario; an approach to no-deal Brexit legislation no-deal Brexit legislation; the Common Travel Area; Medicines and Transport Connectivity.
Legislation required in a no-deal Brexit scenario

The Government had a detailed discussion on its approach to legislation to mitigate some of the most damaging effects of a no-deal Brexit. An outline approach was published, based on a full review of Irish legislative provision, in the No-Deal Continuity Action Plan on 19 December*.

Government agreed that, aside from the European Parliament Elections (Amendment) Bill 2018 and the Regulated Professions (Health and Social Care) (Amendment) Bill, legislation across different sectors be grouped into one omnibus Bill, in order to assist with the speed of passage through the Houses. The Bill, comprising 17 Parts, will focus on the broad themes of protecting enterprise and jobs. Nine Departments in what has been termed the Statutory Instruments covering a range of matters to mitigate a no-deal Brexit.

Update on Common Travel Area (CTA)

The CTA is a long-standing arrangement between Ireland and the UK, which means Irish citizens can move freely to live, work, and study in the UK on the same basis as UK citizens and vice versa. It provides for associated rights and privileges including access to employment, healthcare, education, and social benefits, as well as the right to vote in certain elections. Considerable progress has been achieved bilaterally with the UK over the past year, involving several Departments in what has been a whole-of-Government exercise.

The CTA is an arrangement that is valued on both islands. Both the Government of Ireland and the UK Government have committed that the CTA will be maintained in all circumstances. The CTA pre-dates Irish and UK membership of the EU and is not dependent on it. The CTA is recognised in Protocol 20 to the EU Treaties, which acknowledges that Ireland and the UK may continue to make arrangements between themselves relating to the CTA, while fully respecting the free movement and other rights of EU citizens and their dependents. Protocol 20 will continue to apply to Ireland after Brexit.

Detailed bilateral work with the UK has continued, including in the social security, health and education sectors. Arrangements relating to immigration continue to be led by the Minister for Justice and Equality, through long-established structures. Ireland’s shared aim with the UK throughout has been to ensure that the necessary arrangements are made in both countries so that the CTA continues to function effectively after the UK leaves the EU – irrespective of whether there is an orderly Brexit, or a no-deal scenario.

Neither Irish citizens in the UK nor British citizens in Ireland are required to take any action to protect their status and rights associated with the CTA. After the UK leaves the EU, both Irish citizens in the UK and British citizens in Ireland will continue to enjoy these rights. Both Governments have committed to undertaking all the work necessary, including through legislative provision, to ensure that the agreed CTA rights and privileges are protected.

Medicines

As part of a whole-of-Government response to Brexit, Minister for Health Simon Harris TD has outlined a comprehensive and coordinated set of preparations to ensure the continuity of health services and supply of medicinal products in the event of a no-deal Brexit. This work involves the Department of Health, the HSE, the Health Products Regulatory Authority (HPRA) and other agencies engaged in intensive Brexit preparedness and contingency planning.

Minster Harris outlined the fact that a wide range of issues are being examined with contingency planning for a range of eventualities underway. A key consideration is to ensure, as far as possible, minimum disruption to health services and that essential services are maintained on a cross-border, all-island and Ireland-UK basis.

In relation to the continuity of supply of medicines in the event of a no-deal Brexit, significant work has already been undertaken by the Department of Health, the HSE, and the HPRA, together with industry, to minimise and address any risks to continuity of supply. The supply chain for medicines is complex, and shortages are an increasing feature of the global medicines landscape faced by all countries on an ongoing basis, irrespective of Brexit.

In 2018, the HPRA developed and launched a multi-stakeholder Medicine Shortages Framework to mitigate the impact of medicine shortages when they occur. This framework is used to manage and address an average of 4% shortage notifications a month. The health system is therefore well placed to anticipate and respond to any additional shortages, should they arise because of Brexit.

There are approximately 4,000 medicines marketed in Ireland, of which 60% – 70% come from, or transit through, the UK. The HSE and HPRA have advised that the supply of a small number of these products may be vulnerable for reasons such as their short shelf life, special storage and transportation requirements, and single supplier reliance. The HSE and HPRA are progressing contingency plans including those involved in the supply of critical medicines, verifying contingency planning to date and, where necessary, identifying clinically appropriate alternatives to these small number of vulnerable products.

Industry, including pharmaceutical companies and wholesalers, has been engaging in extensive planning for Brexit for some time and advanced arrangements are in place to ensure continuity of supply. Both the HPRA and HSE are working closely with companies to highlight any issues regarding the availability of specific products associated with Brexit. To date, no major issues have been identified through this process.

The Department of Health, HSE and HPRA do not anticipate an immediate impact on medicine supplies should there be a no-deal Brexit on 29 March. There are already additional stocks of medicines routinely built into the Irish medicine supply chain, and these additional stocks, together with planning by Revenue to allow the fast-tracking of essential drugs into Ireland, will help deal with any delays and shortages that may arise.

It is important to note that the Department has said that there is no need for hospitals, pharmacists or patients to order extra quantities of medicines, as doing so could disrupt existing stock levels and hamper the supply of medicines for other patients.

Transport connectivity

Currently, trade between the UK and Ireland is relatively frictionless as it is all within the Single Market. With the UK potentially becoming a third country from 29 March 2019, substantial additional customs, agriculture, health controls will be required at ports and airports that involve trade with the UK. The main pinch-points are likely to emerge in Irish, UK and French ports – in particular, Dublin, Rosslare and Dover-Calais.

The Department of Agriculture, Food and the Marine, the Department of Health and the Revenue Commissioners are already preparing by developing the necessary plans within Dublin and Rosslare Ports and Dublin airport to allow for these controls. The scale of the checks required will likely result in delays for goods moving through the ports but there is a focus on preventing congestion through the provision of appropriate measures.

The Minister for Transport, Tourism and Sport has assessed the maritime capacity for direct sailings between Ireland and continental EU ports as a potential alternative for trade that currently takes place using the Landbridge. Based on consultations with the shipping sector and wider stakeholders, the Minister’s preliminary assessment is
that sufficient capacity will be available on direct routes to continental ports from end of March 2019, and should demand for further capacity arise, the shipping sector can respond quickly to meet such demands.

The Minister also raised a number of other potential risks to transport connectivity from a no-deal Brexit, and notes the temporary mitigation measures proposed by the European Commission in a no-deal scenario to ensure basic connectivity for flights between the EU and UK, as well as its proposals to facilitate the continuation of international road haulage between the EU and UK.


**Health Products Regulatory Authority (HPRA)**

Following the UK’s triggering of Article 50 to leave the European Union, the HPRA, together with medicines agencies in Europe, is making preparations to ensure that they continue to deliver on their patient and animal health remit, even if the UK fully exits the current systems on 29 March 2019. There are potential implications for the European network as a whole and particularly for Ireland with its shared marketplace.

The HPRA is actively involved in the ongoing planning to ensure the continued supply of medicines after Brexit and this includes working with the Department of Health and the HSE, as well as engagement with wholesalers, pharmaceutical companies and industry representative groups to ask them to review their supply chains in the light of a potential disorderly Brexit. The HPRA has an existing Medicine Shortages Framework in place, the aim of which is to help avert potential shortages from occurring and to reduce the impact of shortages on patients by co-ordinating the management of potential, or actual, shortages as they arise. This framework is used to manage and address an average of 45 shortage notifications a month. The HPRA’s current list of resolved shortages (for the past six-month period) contains a list of 24 medicines and can be viewed on www.hpra.ie.

The key risk to medicines supply, presented by a disorderly Brexit, is due to potential delays at customs. The HPRA and HSE have advised that the supply of a small number of products may be vulnerable, with particular consideration being given to radioisotopes, medicines subject to cold storage and products that require specialised manufacturing processes.

The HSE and HPRA are contacting the associated suppliers to ensure contingency plans are in place for Brexit. In addition, they are working with the Revenue Commissioners to ensure that any delays at customs are minimised. Regardless, their distribution system already holds sufficient stocks to help absorb any short-term delays that may arise. Furthermore, as an additional safeguard, consideration is being given to those categories of medicines which are considered most essential in the clinical setting. While the HPRA is responsible for the authorisation of medicines, decision making in respect of treatment options is part of healthcare provision, and as such is outside of the remit of the HPRA. The role of the HPRA is focused on contacting suppliers of those categories of medicines identified and to seek assurances on the impact of their continued supply in the event of a disorderly Brexit. Work on this iterative process is ongoing and will continue for the foreseeable future. To date, the HPRA has not been informed of any potential shortages due to Brexit. Should any potential issue be identified, they will then utilise their existing shortages framework, outlined above.

During the past two years, the HPRA has proactively engaged with key stakeholders to identify issues affecting UK-based supply chains and to support pragmatic or innovative solutions to potential regulatory barriers. Additionally, during this time their detailed Brexit planning has included:

- Participating in the ongoing discussions at European level for Brexit preparedness and seeking to ensure that the specific needs of the Irish market are recognised and addressed;
- Working with the pharmaceutical and medical device industries to ensure the timely implementation of any regulatory changes for health products arising due to the UK withdrawal. This has included the provision of significant levels of advice on how best to approach the challenges associated with Brexit;
- Increasing their commitment to the assessment of applications to market medicines within the European regulatory network;
- Exploring opportunities for joint labelled packaging with other European markets; and
- Working with UK regulators to help maintain, if needed, joint labelling for products that are on both the UK and Irish markets.

All of the Brexit planning to date by the HPRA has involved proactive actions to facilitate the continued supply of health products and to minimise the impact on patients and healthcare professionals.

**NOTE:** While the HPRA regulates the distribution of medicines in Ireland, the supply routes for medicines are a matter for individual companies provided that compliance with regulatory requirements is ensured.

The HPRA has no role in the procuring, pricing or selection of medicines within the health service in Ireland.

**Irish Pharmacy Union (IPU)**

The IPU is working closely with the Department of Health, the HSE, the HPRA and all stakeholders involved in the supply chain of medicines, to plan for any potential disruptions to medicine supplies as a result of Brexit. The Department of Health, the HSE and the HPRA, are facilitating ongoing engagement with everyone involved in the medicine supply chain, including manufacturers, wholesalers and pharmacists, to identify any potential issues that could affect the supply of medicines and to develop solutions to protect medicine supplies to Irish pharmacies and patients.

We have received assurances that everything that can be done is being done to anticipate, plan for, and mitigate against any potential problems that may arise, and to develop solutions to protect medicine supplies to Irish pharmacies and patients, with a particular focus on the supply of those that have been identified as critical medicines. The IPU is working with the Department of Health, the HSE and the HPRA on ensuring that supplies of such critical medicines are protected.
A recent decision of the High Court examined the decision by the Health Service Executive (HSE) to refuse to enter into Community Pharmacy Contractor Agreements (Contracts or CPCA).

**Summary**

The case concerned two new pharmacies operated by a pharmacy group which had a number of pharmacy premises which already had Contracts with the HSE. The group sought to open two additional pharmacies and applied to the HSE for Contracts in relation to these pharmacies. Ultimately, the HSE refused to conclude Contracts in relation to the two new pharmacies.

The pharmacy group challenged this decision, by way of Judicial Review to the High Court, which held in favour of the HSE.

**Background**

Darastream Limited operates a number of pharmacies in the Leinster area. The company had planned to open two further pharmacies in the Dublin area and applied to the
Key points

- As a general rule, the HSE has the freedom to contract in much the same way as commercial entities.
- There is no positive obligation on the HSE to enter into an agreement if it has a good reason not to.
- There may be cases where there is a good argument that there is a form of obligation on the HSE but this would be on a case-by-case basis.
- Some of the aspects examined by the High Court demonstrate that the CPCA is very much in need of reform and updating.

The HSE alleged that the pharmacy group had a number of issues of concern to it including one pharmacy ordering High Tech stock in the absence of Nominated High Tech Patients; offering of inducements to place orders at the new premises; duplicate cross-pharmacy claiming; overings issues; submission of claims without retaining copy prescriptions; failing to maintain appropriate pharmacy and patient records; and data protection issues. These allegations were merely that, just allegations, and had not been proven by the HSE prior to the judgment.

Following receipt of the application for a CPCA by the pharmacy group, the HSE wrote to its directors in March 2017 to confirm that it was not happy to put in place a new CPCA for each of the new locations, until the Clause 15 process had been concluded in relation to the matters outlined above.

Following this, there was some considerable correspondence between the HSE and the solicitors for the pharmacy group, in which the group sought to have the HSE complete the application for the new agreements without any further delay. It appears that the HSE maintained the position throughout this time, that it did not wish to complete the process and make a final determination regarding the new CPCAs, until it had concluded its Clause 15 process in relation to the other pharmacies. However, following further correspondence from the solicitor for the pharmacy, the HSE decided not to put CPCAs in place with the pharmacy group in respect of the new pharmacies.

Considerations of the High Court

Legislative Provisions

The High Court examined the powers of the HSE under a number of the Health Acts and also examined other relevant issues from the case, including the reasons given by the HSE for refusing to enter into an agreement, the role of the superintendent pharmacist in the process, and the issue of fair procedures in the process.

In relation to the powers of the HSE under the Health Acts, the High Court examined the applicability of various sections and found that the HSE clearly had the power to enter such agreements but that the basis on which it could do so had changed over the years, particularly since the introduction of the Financial Emergency Measures in the Public Interest Act (FEMPI).

It also considered the now revoked Health (Community Pharmacy Contractor Agreement) Regulations 1996 (the Regulations), and whether any conditions in the Regulations may have demonstrated an intention to impose an obligation on the HSE to conclude an agreement with a pharmacy, where it can demonstrate that it satisfies certain conditions and has demonstrated a public health need for the pharmacy. The Regulations have now been revoked and the Court held that, in any event, they would not have placed such a positive obligation on the HSE.

Ownership and connected companies

It was argued, in this case, that the HSE ought not to have taken into consideration issues relating to the Clause 15 procedure which was ongoing in relation to a number of companies which operated pharmacies, and which had the same beneficial owner as Darastream Limited. The High Court held, however, that the HSE is entitled to take into consideration, issues with companies with whom it has CPCAs and which have the same beneficial owner as an applicant company. The Court

“With the High Court having now had an opportunity to consider some of the aspects of the CPCA [...] what is certainly clear is that the CPCA, being almost 25 years old, is very much in need of review.”
held that this would be an effective and efficient use of the HSE’s resources.

It held that the preferred course for the HSE was to defer any decision on Darastream Limited’s application until the Clause 15 procedure had been completed in relation to the connected companies. The decision of the HSE to refuse the application was only made following considerable correspondence with the applicant company.

Superintendent Pharmacist

It was also argued that the request in the application for the identity of the supervising pharmacist, and not the superintendent pharmacist was significant, and indicated that the HSE did not consider the identity of the superintendent pharmacist as being of particular relevance.

The HSE argued that, in fact, the CPCA and the terminology used in it and its related documentation were first drafted in or about 1996, well in advance of the statutory definition of “superintendent pharmacist” contained in the Pharmacy Act 2007. It was submitted by the HSE that the term, supervising pharmacist could be unaware it was, “difficult, however, to imagine how an experienced pharmacist could be unaware of the importance of the superintendent pharmacist in the regulatory regime for pharmacies.”

The court also rejected a connected argument, finding instead that the HSE was under no obligation to grant the CPCA but amend its terms to provide that there be a different superintendent pharmacist in the new pharmacy.

Impact on pharmacies/pharmacists

In the above case, and previously in Collooney Pharmacy Limited v Minister for Health, the High Court has demonstrated that its view is that, as regards entering into the agreement with the HSE, the High Court will assess this from the view of, primarily, ordinary contractual principles, i.e. the freedom of parties to contract with whomever they choose.

However, the fact remains that the HSE does have an obligation under the Health Acts to provide the public with access to healthcare and medicines. Therefore, in different circumstances, perhaps in an area which is much more sparsely serviced than Dublin, there may be an argument to be made that failing to enter into a CPCA with a pharmacy may be a breach of the HSE’s obligations. This, however, would have to be assessed strictly on a case-by-case basis.

It remains to be seen, whether the decision will be appealed. There are very few High Court cases relating to community pharmacy, and fewer still which consider aspects of the CPCA. With the High Court having now had an opportunity to consider some of the aspects of the CPCA, amongst them the fact that it was introduced before many of the modernisations of the profession, including the introduction of the role of Superintendent Pharmacist and the enactment of the Pharmacy Act 2007, what is certainly clear is that the CPCA, being almost 25 years old, is very much in need of review.

The regulatory and disciplinary team at DAC Beachcroft Solicitors (01 2319600) led by Gary Rice (grice@dacbeachcroft.com) specialises in the commercial and regulatory issues which arise for pharmacies and pharmacists. DAC Beachcroft, a global law firm, is a recognised market leader in healthcare law. This article is for general information purposes only and does not comprise legal advice on any particular matter. You should not rely on any of the material in this article without seeking appropriate legal advice.

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PSI looks to the future in its final council meeting of 2018

Staffing issues, budgets and the future strategic agenda and changing structure of the PSI were the dominant themes at its December 2018 Council meeting.

The 2018 Service Plan implementation report for the year, from PSI Registrar Niall Byrne, was one of the key documents presented at the meeting. Of the 23 Council-approved actions for 2018, nine were fully completed, 10 were as close to completion as possible, three did not achieve the level of progress hoped for, and one did not progress, largely down to a lack of resources, he said, but this will be carried over into this year.

Mr Byrne said he believed that the results for 2018 were satisfactory and represented what could be realistically achieved with the resources available. He acknowledged the contribution of all PSI staff and the guidance of the Council in achieving these results in a very challenging year.

Furthermore, the growing staffing needs of the PSI were emphasised by Mr Byrne, who reminded Council members that they had agreed back in September 2017 that 15 new posts were required, and the Council had been working with the Department of Health since then, submitting a business case in March 2018 to have them sanctioned. It was only in the week before this meeting that the Department confirmed they were going to sanction seven posts, he told the meeting, which, while short of what was needed, was welcome, with plans to continue pressing for the remaining requested posts in early 2019. He also confirmed the PSI’s new HR strategy had been finalised and would be published shortly.

While the PSI’s ongoing work on its future strategic direction was heavily discussed, it was pointed out by the Registrar that its structure was equally important, with the current structure no longer appropriate for its remit.

A good part of the meeting was dedicated to hearing updates (including various business cases and consultation processes) from the sub-committees and Registrar on the significant structural changes the PSI will undergo, i.e. its ICT business transformation process which includes the PSI engaging with other relevant agencies about their digital transformation for advice.

In addition, there was a lot of discussion and questions over the need to finish tidying up the legacy of the old PSI structure (from when it went from a self-regulatory body to a statutory regulator), to create a stand-alone professional development body – so the future structure would be like the current one for doctors in Ireland; with the Medical Council, representative bodies like the IMO, and training bodies like the Irish College of GPs. It was explained that while the Irish Institute of Pharmacy (IIOP) has overseen CPD requirements for pharmacists since 2013, it is just a contracted body and does not have the scope to independently provide the necessary full range of professional, leadership and research services for the profession. Thus, research on how to go about creating an independent professional development body for pharmacy in Ireland and consultation with the various stakeholders, needs to be carried out.

However, there was some debate over the sanction of up to €120,000 for this consultation process, particularly when the financial position of the Council was outlined for 2019 and revealed a significant projected six-figure deficit. It was emphasised by the Council’s Administration and Finance Committee head, Shane McCarthy, that the Council’s costs had been gone through very carefully, and outgoings were tightly controlled, but it was a fact that the Council’s income remained static despite its rising costs and major redevelopment projects. The pressing need to increase the Council’s income has been communicated to the Department of Health. The 2019 budget and service plan were adopted by the Council following some further discussion.

Not surprisingly, the Council’s discussion of its amended draft of planned changes to the rules relating to the temporary absence of pharmacists generated some lively debate. A small number of pharmacy assistants, who would be very negatively affected by the planned rule changes, sat in the public gallery during the meeting to hear the Council’s discussion on the matter. It was agreed that the PSI would undertake a final public consultation.
process on its amended proposals (which was launched before Christmas and closed on 11 January 2019), before they would be signed off on and sent to the Minister for Health for approval. It was noted that the previous consultation process last summer generated a big response (over 1,000 submissions), though one Council member voiced dismay that the concerns raised, regarding the impact of the rule changes in response to that consultation process, had been ignored, while others asked was there any point in further consultation if the rule changes were to proceed as planned. Council Vice-President Nicola Cantwell said she felt the planned changes would remove the ability of pharmacy assistants to dispense most medicines and really limit their role, and were akin to “using a hammer to crack a walnut”. Other members asked for clarity on the impact of the changes, and it was agreed that a detailed explanation document would have to be provided to all pharmacies in line with the rule changes notification when they are enacted.

The Registrar reminded members that the Council’s key function was ensuring patient safety, and that was the basis behind the planned changes.

Meanwhile, Mr Byrne confirmed that he and the PSI’s head of policy had “a very, very positive meeting” with Ms Laura Magahy, Executive Director of the Sláintecare Implementation Programme, in October and presented her with the key recommendations of the PSI’s Future Pharmacy report. He said she was very interested in seeing how pharmacy could help contribute to the Sláintecare agenda, and deliver care closer to where people live in the community, helping shift the emphasis of the health service more towards primary care. Mr Byrne said he hoped to have more engagement with Ms Magahy in 2019.

He also noted that there is a keen need for a new pharmacist contract, pointing out that the old one is over 22 years old now and is clearly no longer fit for purpose. While the Department acknowledges this, Mr Byrne said it is likely to be some time before anything happens, as the new GP contract will be first on the agenda.

Meanwhile, there was a brief discussion about the PSI’s social media presence and how it was being carefully used to increase its profile and inform the public, and other stakeholders, about the PSI’s regulatory work. There was also mention of the PSI’s exploration work on the use of behavioural economics and the nudge theory for public bodies.

"While the PSI’s ongoing work on its future strategic direction was heavily discussed, it was pointed out by the Registrar that its structure was equally important, with the current structure no longer appropriate for its remit.”
Role of pharmacists in abortion services debated as legislation finalised

In finalising the legislation, there was widespread discussion in the Oireachtas regarding conscientious objection from pharmacists. Senator David Norris (Independent), raised concerns that he, “had contact from a number of pharmacists who stated that the Code of Conduct for Pharmacists 2009 and the draft code, published in June 2018 but not adopted, clearly show that pharmacists’ rights to freedom of conscience are nowhere mentioned or protected.” He argued that, “I do not believe that allowing doctors the complete freedom of conscience and extending this to cover pharmacists would inhibit the implementation of this legislation.”

Senator Brian Ó Domhnaill (Fianna Fáil) outlined how “the Irish Pharmacy Union wrote to the Minister to outline its grave concerns about the same issue on 28 February 2018. These concerns have not been addressed. The code of conduct of the Pharmaceutical Society of Ireland, which has been referred to as a way of protecting pharmacists, does not refer to conscientious objection or freedom of conscience, religion or belief.”

John Brassil TD (Kerry, Fianna Fáil) outlined the important role pharmacists will play in dispensing the required medications. “Dispensing drugs is not like handing out chips in a chip shop; rather, it is an issue of professional responsibility, particularly in hospitals. I am informed that the drug, potassium chloride, may be needed at a later stage during pregnancy. As it is highly toxic, it is highly controlled in its prescription, dispensing and administration to avoid inadvertent toxicity or death. The role of the pharmacist in its dispensing, if it is to be used in an abortion, is extremely important.”

Speaking in the Senate, Minister for Health Simon Harris TD, responded to these concerns stating, “The Bill and existing medical guidelines make it clear that conscientious objection cannot be invoked in an emergency situation where there is a risk to a pregnant woman’s life or health and where there is an immediate risk in that regard.” Specifically relating to pharmacists, Minister Harris outlined how “the PSI has approved a new code of conduct for pharmacists. Part five of principle four, on page nine of the proposed code of conduct, makes provision for conscientious objection subject to a referral of a patient to an alternative provider if a pharmacist cannot provide a professional service or a medicinal product so that patient care is not jeopardised or compromised.”

Since the first of January, abortion services have become available in Ireland, with a level of service available in all 19 maternity hospitals as well as over 200 GP practices.
Orphan drugs debated

A Private Members Bill, introduced by John Brassil TD (Kerry, Fianna Fáil), has been debated in the Dáil. The Health (Pricing and Supply of Medical Goods) (Amendment) Bill 2018 aims to establish specific criteria applicable for orphan medicinal products for the purposes of the Health Service Executive making a relevant decision regarding adding an item to the Reimbursement List.

Outlining the requirement for this Bill, Deputy Brassil said, “In recent years, it has become clear that there is an issue in Ireland whereby orphan drugs continually struggle to secure reimbursement here, often despite their wide availability elsewhere in Europe. This reimbursement process is protracted, unnecessarily public and often antagonistic, with patients continually forced to protest publicly or engage with politicians to seek fairness and equity over the course of a two-year campaign from initial application in Ireland to its final decision. “This is not to suggest that we should not carefully consider orphan drugs. Rather, we should look to EU member states such as Sweden, which has adapted its health technology assessment process in such a manner. In addition, the Bill places on a statutory footing, some important considerations for the HSE to assess before making a final decision on an orphan drug. These include the availability of the drug elsewhere in Europe, guaranteed input of patients and the level of certainty that can be provided by industry through risk-sharing agreements.”

There was support for the Bill from Lisa Chambers TD (Mayo, Fianna Fáil), who said, “We know the current system is not working. In recent years, drug after drug has been debated at length in the House. We have had Orkambi and Respreeza and now we have Spinraza. More and more orphan drugs for rare diseases will continue to surface. Every month and every year they will come down the tracks.”

Other colleagues of Deputy Brassil also spoke in support of the Bill, including Mary Butler TD (Waterford, Fianna Fáil) and James Browne TD (Wexford, Fianna Fáil). While Labour Health Spokesperson, Alan Kelly TD (Tipperary), was also vocal in his support saying, “This is absolutely necessary. We have to change quickly what we are doing in regard to orphan drugs. If we do not, we will let down people all over the country.”

Minister Harris said that “I certainly do not argue with the spirit of the Bill. It is one which has been tabled with the intention of ensuring faster access for patients to orphan medicines which, I assure the House, is also a goal of mine.” Minister Harris committed to continue to work with Deputy Brassil on these issues, but raised concerns about how the Bill “would fundamentally change the statutory reimbursement criteria for orphan medicines”.

Meanwhile, during a meeting of the Health Committee on the topic of orphan drugs, Dr Derick Mitchell, CEO of the Irish Platform for Patient Organisations, Science and Industry, said he “would like to see greater interaction between clinical and pharmacy communities on those decisions because we feel that pharmacists have a role to play. Maybe not as the decision-makers but, certainly in terms of the decision itself, there should be more collegiality between the two communities on that aspect.”
Biosimilar policy still under consideration

John Brassil TD (Kerry, Fianna Fáil) has queried the Government’s actions to increase the use of biosimilars to reduce the cost of medicines.

Responding, Minister Harris said that his Department was considering the responses to a 2017 public consultation on a National Biosimilar Medicines Policy. According to the Minister, these responses will support the development of a National Biosimilar Medicines Policy.

Minister Harris added that, “At an operational level, the HSE’s Acute Hospitals Drugs Management Programme has a biosimilar strategy in place since 2017, which is making considerable progress using a collaborative approach led by hospital pharmacists.”

Role of pharmacies in Warfarin treatment

Pharmacies can play a bigger role in supporting patients on Warfarin, while also delivering cost savings for the State, Kate O’Connell TD (Dublin Bay South, Fine Gael), has said.

“There can be efficiencies built in with Warfarin as for haemochromatosis. Giving the flu vaccine in pharmacies worked well, the morning after pill has worked, and any interventions the Chairman and the Minister of State have made to make it available at the weekend have worked. We have evidence that when initiatives are moved into the community, they can be more efficient in themselves but also reduce burden of disease as well.”

She went on to outline how incorrect prescriptions and errors were a major reason for nursing home and hospital admissions. In the UK, she said, “There is an incentive for pharmacists in the UK whereby if they make an intervention in a prescription, for example, bringing 12 meds down to six without interfering with doctor’s orders, they get something like £5. It is not very much, but there is an amount available to make it worth one’s while to do the paperwork. That kind of approach has to be considered. Sláintecare is all about moving from acute care to primary care. However, looking at the big picture, what is being done? The money will run out and services will be cut in the future if they are not bedded down into the community.”

In response to these comments, Minister of State Jim Daly TD, (Cork South West, Fine Gael), described the suggesting as interesting initiatives that provide “normal rather than distorted incentives for good, common efficiencies in the prescribing and administration of drugs.”

Reimbursement of pneumococcal vaccines

Sinn Féin Health Spokesperson, Louise O’Reilly TD (Dublin Fingal), has questioned the Minister for Health on the reasons that the pneumococcal vaccine “when administered by pharmacists is not reimbursed for eligible patients in the same way as the flu vaccination.”

In response, Minister Harris confirmed that, “the expansion of pharmacy-provided vaccination for public patients, in order to make such treatment as accessible as possible” was among the considerations of his Department in considering expansions to the role of pharmacies.

However, the Minister also said there were no plans to provide reimbursement for the administration of pneumococcal vaccine when administered by pharmacists. He cited that “the recommendations for the seasonal influenza and the pneumococcal vaccination programmes differ in the recommended groups and the number of doses required.”

Pharmaceutical assistants continue to be raised

The impact of PSI proposals on the role of pharmaceutical assistants continues to be raised in the Dáil.

Kate O’Connell TD (Dublin Bay South, Fine Gael), has asked the Minister for Health about “the person or body that will be responsible for paying redundancy to the persons who lose their jobs.”

The Minister explained, “My role in relation to this process is limited to the consideration of any such Rules once submitted for my approval. I must consider any Rules presented to me from a fair and impartial perspective, without prejudice or prejudget.”

Minister questioned on expanding the role of community pharmacies

Minister Simon Harris has faced further questions from both John Brassil TD (Kerry, Fianna Fáil) and Louise O’Reilly TD, (Dublin Fingal, Sinn Féin), about expanding the role of community pharmacy.

Deputy Brassil asked the Minister of, “his plans to help community pharmacists expand their services and if he will make a statement on the matter.”

The Minister outlined, as he had done previously, “The Programme for Partnership Government is committed to expanding the role of community pharmacy, where this can provide better outcomes for public patients. New public services in community pharmacy, if introduced, should improve health outcomes and provide value for money and benefits for patients. Any new or transferred services should be based on sound evidence with matching improvements in governance and administration.”

Meanwhile Deputy O’Reilly raised the topic of the Minor Ailments Scheme, asking, “the reason the publication of the findings of the 2016 pilot for a Minor Ailments Scheme was delayed; the timeframe for delivery of the proposals; and if consideration will be given to running an extended pilot to facilitate the collection of additional data.”

The Minister responded that the report is being examined by his officials.

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The IPU Product File is an open system, so no matter what vendor you choose, the product file is the same format, so you can compare competitors easily.

Easy to use

The audit and certification process for ISO Certification of the IPU Product File team are available to answer your queries, whether it’s ordering, stock taking, price checking and product sourcing.

The audit and certification process for ISO Certification for 9001 (Quality) and 27001 (Information Security).

In 2016, the IPU Product File achieved ISO Certification Registered ISO 9001 Registered ISO 27001 Management Management

IPUREVIEW FEBRUARY 2019

Front of Shop products (shampoos, toothpastes, vitamins etc.)

Photographic products

Veterinary products

Unlicensed medicinal products

IPU PRODUCT FILE

For any queries relating to the IPU Product File, please contact a staff member at datainfo@ipu.ie or 01 406 1550.

The IPU Product File team are available to answer your queries, whether it’s ordering, stock taking, price checking and product sourcing.

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IPU PRODUCT FILE

The IPU Product File has been in existence for more than 30 years and is an indispensable resource for community pharmacists. It was designed for pharmacists by pharmacists and is also used by doctors and hospital personnel. It is a vital support tool for prescribing, dispensing, claiming with PCRS, stock ordering, stock taking, price checking and product sourcing.

What is in the File?
The File contains information on over 63,000 products, including:

- Licensed medicinal products
- Unlicensed medicinal products
- Medical devices and sundries (bandages, dressings, ostomy equipment etc.)
- Nutritional products, including foods for special diets
- Veterinary products
- Photographic products
- Cosmetic products
- Front of Shop products (shampoos, toothpastes, vitamins etc.)

In addition to pricing information, barcodes etc., the IPU Product File provides valuable professional information on health products. The professional information provided includes the Medicinal Product Name, PA/EU number, Generic Name, Pharmaceutical Form, Strength and Legal Status.

ISO Certified
In 2016, the IPU Product File achieved ISO Certification for 9001 (Quality) and 27001 (Information Security). The audit and certification process for ISO Certification emphasises the robustness of the IPU Product File and underpins its position as the definitive medicinal product catalogue in Ireland.

Easy to Use
The IPU Product File is an open system, so no matter what vendor you choose, the file can be adapted for your needs. The IPU Product File is available by electronic download, where you can log-in and download your monthly update.

Contact Us
The IPU Product File team are available to answer your queries, whether it’s on sourcing a product, pricing queries etc., the team will be able to assist you.

For any queries relating to the IPU Product File, please contact a staff member on 01 406 1550 or datainfo@ipu.ie
**STUDIES**

**New England Journal of Medicine publishes positive detailed results from Praluent® (alirocumab) cardiovascular outcomes trial**

The trial met its primary endpoint, showing that Praluent® (alirocumab) significantly reduced the risk of major adverse cardiovascular events (MACE) in patients who had suffered an acute coronary syndrome (ACS), which included a heart attack or unstable angina. MACE occurred in 903 patients (9.5%) in the Praluent group and in 1,052 patients (11.1%) in the placebo group (HR 0.85; 95% CI, 0.78 to 0.93; p<0.001).

Death from any cause was less frequent among Praluent-treated patients. Praluent was associated with a 15% lower risk of death; death occurred in 334 (3.5%) patients in the Praluent group and 392 (4.1%) patients in the placebo group (HR 0.85; 95% CI, 0.73 to 0.98).

The NEJM publication also includes results for MACE and other secondary endpoints including death, according to subgroups of baseline LDL-C (low-density lipoprotein cholesterol) levels, which are described in detail in the Supplementary Appendix. The data showed that patients with higher LDL-C at baseline (at least 100 mg/dL) were at greater risk of MACE, as well as other secondary endpoints including death. Moreover, the greater risk reduction occurred in this category of patients; in the Praluent group, MACE was reduced by 24% (HR 0.76; 95% CI, 0.65 to 0.87) and death from any cause was 29% lower (HR 0.71; 95% CI, 0.56 to 0.90) compared to placebo.

Adverse events were similar between groups except for injection site reactions (Praluent 3.8%, placebo 2.1%).

The effect of Praluent on cardiovascular morbidity and mortality is currently being reviewed by regulatory authorities and has not yet been fully evaluated. Data from the ODYSSEY OUTCOMES trial has been submitted to regulatory authorities in the European Union and in the U.S., where the target action date for the Food and Drug Administration (FDA) decision is 28 April 2019.

**References**

1. Analyses for the death endpoints in the overall study fell outside of the statistical hierarchy; and in accordance with recently implemented NEJM policies, the hazard ratio (HR) and its confidence interval (CI) were published, but no P-values were reported.

2. Analyses of the death endpoint based on baseline LDL-C levels were not included in the statistical hierarchy; and in accordance with recently implemented NEJM policies, the hazard ratio (HR) and its confidence interval (CI) were published, but no P-values were reported.

**NANOBIOTIX: Positive Phase II/III results for NBTXR3 in soft tissue sarcoma presented at ESMO**

NANOBIOTIX (Euronext: NANO – ISIN: FR0011341205), a late clinical-stage nanomedicine company pioneering new approaches in the treatment of cancer, presented NBTXR3 positive Phase II/III Act.in.sarc results in patients with locally advanced soft tissue sarcoma at the European Society for Medical Oncology (ESMO) 2018 Congress (Munich, Germany) during the Proffered Paper Oral presentation of the sarcoma section (LBA66).

NBTXR3 is a first-in-class product with a new mode of action designed to physically destroy cancer cells when activated by radiation therapy (RT). NBTXR3 is designed to directly destroy tumours and activate the immune system for both local control and systemic disease treatment.

In the Phase II/III Act.in.sarc study, a total of 180 adult patients with locally advanced soft tissue sarcoma of the extremities or trunk wall were randomly allocated, in a 1:1 ratio, to either (i) Arm A, and received a single intratumoral injection of NBTXR3 at the recommended dose (10% of baseline tumour volume) followed by radiation therapy or (ii) Arm B, the control arm, and treated with radiation therapy alone. In both arms, radiotherapy was followed by surgery. The primary efficacy analysis was performed on the intent-to-treat population following the Full Analysis Set principle (ITT-FAS) population as per protocol.

**Pathological Complete Response Rate (pCRR): the study met its primary endpoint**

The study met its primary endpoint with a pathological complete response (<5% viable cancer cells) rate of 16.1% in the NBTXR3 arm vs 7.9% in the control arm (p=0.0448). In addition, in the subgroup of patients with a more advanced disease (histologic grade 2 and 3) pathological complete response was achieved in four times more patients in the NBTXR3 arm than in the control arm (17.1% vs 3.9%). An increase in the proportion of patients with a pathological response regardless of the pre-defined cut-off was observed in Arm A. The proportion of patients with pathological nearly complete response (<7% of viable cancer cells) and pathological response with 10% or less of viable cells were 24.7% and 34.6%, respectively, in the NBTXR3 arm vs 14.8% and 19.8% in the control arm.

**R0 resection margin: the study met its main secondary endpoint**

The main secondary endpoint of carcinologic resection was also met with R0 resection margin achieved in 77% of the patients who received NBTXR3 compared to 64% of patients in the control arm (p=0.0424).

**Tumour necrosis/infarction: the study also met this secondary endpoint**

Histologic analysis showed that the mean percentage of tumour necrosis/infarction was also increased in the NBTXR3 arm compared to the control arm (28.8% vs 19.2%; p=0.014).

**Safety profile similarity across study arms**

Similar safety profiles were observed in the NBTXR3 arm and the radiation therapy alone arm. NBTXR3 did not impact the patients’ ability to receive the planned dose of radiotherapy and the radiotherapy safety profile was similar in both arms, including the rate of postsurgical wound complications. NBTXR3 was associated with grade 3-4 acute immune reactions in 7.9% of patients, which were manageable and of short duration. NBTXR3 showed a good local tolerance and no impact on the severity or incidence of radiotherapy-related adverse events.

Long-term follow-up of the patients is ongoing to evaluate the Time-to-Local/Distant Recurrence and Local/Distant Recurrence Rate (LRR/DRR) at 12 and 24 months.

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Long-term follow-up of the patients is ongoing to evaluate the Time-to-Local/Distant Recurrence and Local/Distant Recurrence Rate (LRR/DRR) at 12 and 24 months.
Treatment of Hepatitis C in Ireland

Hepatitis C is a viral infection which causes inflammation of the liver. It is spread through contact with the blood of an infected person. Sharing injecting needles and equipment with someone who is infected is the most common way to get Hepatitis C in Ireland. It became a notifiable disease in Ireland in 2004.

New treatments for HCV (Hepatitis C Virus) have become available in recent years using direct acting antivirals, with courses of treatment of only 8 to 12 weeks.

There are two treatment regimens used in Ireland to treat HCV infection in adults; Epclusa 400mg/100mg film-coated tablets, and Maviret 100mg/40mg film-coated tablets. While they are both 100mg/40mg film-coated tablets, and Maviret 300mg/120mg is three tablets. While they are both generally well tolerated, there are considerable contraindications and drug-drug interactions to consider.

Epclusa

Epclusa tablets contain 400mg of sofosbuvir and 100mg of velpatasvir.

Sofosbuvir is a pan-genotypic inhibitor of the HCV NS5B RNA-dependent RNA polymerase, which is essential for viral replication.

Velpatasvir acts as a HCV inhibitor by targeting the HCV NS5A protein, which is essential for both RNA replication and the assembly of HCV virions.

The recommended dose of Epclusa is one tablet, once daily, with or without food for 12 weeks. Addition of ribavirin (another direct acting antiviral for the treatment of HCV) may be necessary depending on cirrhosis and genotype — further information on this is included in the SmPC.

If vomiting occurs within three hours, an additional tablet of Epclusa should be taken. The tablets should be swallowed whole and not chewed or crushed due to the bitter taste.

Contraindications and drug interactions

Epclusa is contraindicated if patients are on medicines that are potent P-glycoprotein (P-gp) or potent cytochrome P450 inducers. This includes rifampicin, rifabutin, St. John’s wort, carbamazepine, phenytoin, and phenobarbital.

Medicines that are moderate P-gp or moderate CYP inducers may decrease levels of sofosbuvir or velpatasvir and co-administration is not recommended. This includes oxcarbazepine, modafinil, or efavirenz.

Velpatasvir is itself an inhibitor of P-gp, breast cancer resistance protein (BCRP) and organic anion-transporting polypeptide. Co-administration with substrates of these transporters may increase exposure of such products.

There is a long table of potential drug interactions in the Epclusa SmPC which should be consulted before any patient is started on therapy. To highlight a few examples: patients on digoxin would require therapeutic drug monitoring; monitoring is recommended with dabigatran due to risk of bleeding; and resovastatin doses must not exceed 10mg due to the risk of myopathy. Additionally, there is an interaction with proton-pump inhibitors due to an increase in gastric pH.

Warnings and precautions for use

Diabetic patients may experience improved glucose control and may require their diabetic medication to be modified accordingly to prevent hypoglycaemia.

As liver function may change during treatment, monitoring of INR is recommended for patients on Vitamin K antagonists.

Hepatitis B virus reactivation can occur during treatment with direct-acting antivirals, and so screening for Hepatitis B should be performed in all patients before start of treatment.

Due to cases of severe bradycardia and heart block, amiodarone should only be used when other anti-arrhythmic treatments are not suitable. Patients on amiodarone taking Epclusa need to be closely monitored in a clinical setting.

Patients on certain HIV antiretroviral regimens should be monitored for adverse reactions, since Epclusa has been shown to increase tenofovir exposure in such cases.

As a precautionary measure, use in pregnancy and breastfeeding is not recommended.

Epclusa is well tolerated — headache, fatigue and nausea are the most common adverse effects reported.

The product is subject to additional safety monitoring, as indicated by the inverted black triangle on the SmPC and in the Package Leaflet. Patients and healthcare professionals are encouraged to report any suspected adverse effects to the HPRA.

Maviret

Maviret tablets contain 100mg of glecaprevir and 40mg of pibrentasvir.

Glecaprevir is a pan-genotypic inhibitor of the HCV NS3/4A protease which is essential for viral replication.

Pibrentasvir is a pan-genotypic inhibitor of HCV N55A, essential for viral RNA replication and virion assembly.

The recommended dose of Maviret 300mg/120mg is three tablets, once daily with food. The recommended treatment duration is eight weeks (no cirrhosis) or 12 weeks (with cirrhosis). In patients with failed prior therapy, the recommendation duration...
may vary and the SmPC should be consulted.

If vomiting occurs within three hours, an additional dose should be taken. The tablet should be swallowed whole, with food, and not chewed, crushed or broken, as this may alter the bioavailability.

Contraindications and drug interactions
Maviret is contraindicated in patients with severe hepatic impairment.

Also contraindicated is concomitant use with atazanavir-containing products, atorvastatin, simvastatin, dabigatran etexilate, ethinyl oestradiol-containing products, and also strong P-gp and CYP3A inducers (examples include rifampicin, carbamazepine, St. John’s wort, phenobarbital, phenytoin and primidone).

Both glecaprevir and pibrentasvir are inhibitors of P-gp, BCRP and organic anion transporting polypeptide. As for Epclusa, co-administration with substrates of these transporters may increase exposure of such products. There is a long table of potential drug interactions in the Maviret SmPC, which should be consulted before patients are started on therapy. Some examples include: the need for therapeutic drug monitoring with digoxin; pravastatin doses must not exceed 20mg; rosvastatin doses must not exceed 5mg; and, as stated above, contra-indications with atorvastatin, simvastatin and dabigatran.

Warnings and precautions for use
In common with Epclusa, diabetic patients may require their diabetic medication to be altered to prevent hypoglycaemia, and monitoring of INR is recommended for patients on Vitamin K antagonists.

Also in common, Hepatitis B screening should be performed before treatment in all patients. Maviret is not recommended in patients with moderate hepatic impairment.

As a precautionary measure, use in pregnancy is not recommended. A decision whether to discontinue breast-feeding or discontinue treatment would need to be made.

Maviret is well tolerated – the most commonly reported adverse reactions were headache and fatigue.

The product is also subject to additional safety monitoring, as indicated by the inverted black triangle on the SmPC and in the Package Leaflet. Patients and healthcare professionals are encouraged to report any suspected adverse effects to the HPRA.
Pelgraz® – Pegfilgrastim Biosimilar

Pelgraz® 6mg prefilled syringe, containing pegfilgrastim, is a biosimilar agent available on the High Tech Medicines Scheme as of 1 December 2018 – High Tech Code 88961.

The reference biological product, Neulasta® 6mg prefilled syringe, has been available on the High Tech Medicines Scheme since 2011 – High Tech Code 88484.

Pelgraz® was authorised by the European Medicines Agency (EMA) in September 2018. The reimbursement price in Ireland is approximately 30% less than that of Neulasta®, offering significant potential cost savings to the State.

Mode of action and therapeutic indications

Pegfilgrastim belongs to the family of medications known as Granulocyte Colony Stimulating Factors (G-CSF). G-CSF is a glycoprotein, which regulates the production and release of neutrophils from the bone marrow. Administration of G-CSF causes a marked increase in peripheral blood neutrophil counts within 24 hours, with minor increases in monocytes and/or lymphocytes.

Pegfilgrastim is derived from recombinant human G-CSF; a 175 amino acid protein expressed in E. coli cells. Polyethylene glycol (PEG) is conjugated to the N-terminal methionine residue of G-CSF. Pegfilgrastim products (Neupogen® and its biosimilars) have a short half-life requiring daily administration until the patient’s neutrophil count has recovered to its normal range, usually 10 – 14 days. The addition of the PEG molecule to filgrastim affords pegfilgrastim with a long half-life, requiring only one injection per chemotherapy cycle.

Pelgraz® has the same therapeutic indication as Neulasta® – reduction in the duration of neutropenia and the incidence of febrile neutropenia in adult patients treated with cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes). As for Neulasta®, one 6mg dose (one single prefilled syringe) of Pelgraz® is recommended for each chemotherapy cycle, given at least 24 hours after cytotoxic chemotherapy. Both products are for subcutaneous use. The injections should be given subcutaneously into the thigh, abdomen or upper arm.

Under the usual approval process for biosimilars, Pelgraz® has been compared to the reference product Neulasta® and it has been shown that the active substance is highly similar in terms of structure, purity and biological activity and is distributed in the body in the same way. A study in breast cancer patients undergoing chemotherapy showed that the effectiveness of Pelgraz® was equivalent to Neulasta® in reducing the duration of neutropenia.

Further information on the comparative studies between Pelgraz® and Neulasta®, that were conducted during the approval process, can be read in the EPAR – European Public Assessment Report, located on the EMA website by searching for Pelgraz® and selecting ‘Assessment History’.

Adverse reactions

Overall, the safety profile was similar and was consistent with the known events associated with pegfilgrastim treatment. The most frequently reported adverse reactions were bone pain (very common) and musculoskeletal pain (common). Bone pain was generally of mild to moderate severity, transient and could be controlled in most patients with standard analgesics. Hypersensitivity-type reactions, including skin rash, urticaria, angioedema, dyspnoea, erythema, flushing and hypotension occurred on initial or subsequent treatment with pegfilgrastim. Serious allergic reactions, including anaphylaxis can occur in patients receiving pegfilgrastim. Pulmonary adverse reactions have been reported. Uncommonly, cases have resulted in respiratory failure.

Pharmacovigilance

As per the HPRA Guide to Biosimilars for Healthcare Professionals and Patients (December 2015), to facilitate traceability, any biological medicine prescribed, dispensed or sold should be clearly identifiable by brand name or as appropriate INN accompanied by the name of the marketing authorisation holder. This will also ensure that substitution of biosimilar medicines does not inadvertently occur when the medicine is dispensed by the pharmacist. Under the Health (Pricing and Supply of Medical Goods) Act 2013, biological medicines are specifically excluded from being added to interchangeable medicine lists. As such, they cannot be subjected to pharmacy substitution as exists for small chemical molecules.

Pelgraz® is subject to additional safety monitoring, as indicated by the inverted black triangle on the SmPC and in the Package Leaflet. Patients and healthcare professionals are encouraged to report suspected side-effects seen with these medicines to the HPRA.

Article 102(e) of Directive 2010/84/EU requires that adverse reaction reports record the brand name or, as appropriate, INN accompanied by the name of the marketing authorisation holder and batch number of the biological medicine prescribed, dispensed, or administered. Pelgraz® 6mg prefilled syringe was added to the IPU Product File with the December 2018 update following addition to the High Tech Medicines Scheme.

High Tech Number: 88961
Scotland

Community pharmacy Scotland report on the success of the Minor Ailment Service

A new report, commissioned by Community Pharmacy Scotland (CPS), demonstrates the undeniable popularity of the Minor Ailment Service (MAS) among patients, with close to 90% of participants rating the overall service 10-out-of-10 for satisfaction and the overwhelming majority rating their experience of consultations as “excellent”.

The Minor Ailment Service is provided by community pharmacies and is available to qualifying groups of people, such as children, those over 60 and people on certain benefits. The service is intended to allow patients to go directly to their pharmacist for minor health concerns and helps people to improve their self-care of certain limiting conditions. It is also intended to combat health inequalities.

The report validates the necessity of this service, with 60% of those who used the service saying they would have gone to their GP if they could not have accessed this service at their community pharmacy. Others said that in the absence of the service they would have bought over-the-counter medicines, would not have treated their condition, would have looked online for guidance or would have gone to A&E. The value of the Minor Ailment Service is clear, for both patients and for the NHS as a whole.

You can find the full published report at www.cps.scot/mas-report.

Source: www.rpharms.com

England

NHS long term plan published

NHS England has published the NHS Long Term Plan, setting out its priorities for healthcare over the next 10 years and showing how the NHS funding settlement will be used.

For community pharmacy, the plan states:

- NHS England will work with the Government to make greater use of community pharmacists’ skills and opportunities to engage patients;
- NHS England and the Government will explore further efficiencies through reform of reimbursement and wider supply arrangements;
- NHS England will work with community pharmacists and others to provide opportunities for the public to check their health through tests for high blood pressure and other high-risk conditions; and
- From 2019, NHS 111 will start direct booking into GP practices across the country, as well as referring on to community pharmacies who can support urgent care and promote patient self-care and self-management.

The plan makes several mentions of pharmacists in particular, noting the role that they will play in local Primary Care Networks. Pharmacists may be involved in helping to identify and treat people with high-risk conditions, undertaking a range of medicine reviews, including educating patients on the correct use of inhalers and offering medicine reviews to care home residents. NHS England has also pledged to offer Primary Care Networks a new “shared savings” scheme, so they can benefit from actions taken such as to reduce avoidable A&E attendances and delayed discharge and to reduce over-medication through pharmacist review.

The plan includes measures to:

- Improve out-of-hospital care by supporting primary medical and community health services;
- Provide better care for major health conditions such as cardiovascular disease, respiratory conditions and diabetes;
- Support those admitted to hospital with smoking/alcohol addiction;
- Support older people through more personalised care and stronger community and primary care services; and
- Make digital health services a mainstream part of the NHS, so that in five years’ time, patients in England will be able to access online GP consultations.

NHS England has also promised to recruit tens of thousands more doctors, nurses and other health professionals, although its full workforce plan is not expected until later this year.

Simon Dukes, PSNC Chief Executive, said, “It is good to see more of what the NHS, community pharmacy’s key customer, wants to achieve in the long term and how it plans to get there. The crucial thing for pharmacy now is to work out how it fits into this, and our next step will be to work with the NHS and Government to explore what community pharmacy’s contribution to the plan will be. We are ready to begin those conversations, and with the NHS now clear on its own 10-year plan, we want to begin negotiations on a similar long-term plan for community pharmacy, setting out how pharmacies can do more, working closely with primary care colleagues, for the benefit of the NHS and patients.”

“We are pleased that NHS England is committed to making greater use of community pharmacists’ skills and look forward to working with them to ensure that this happens. In our contributions to the NHS plan, we and the other pharmacy organisations set out a range of ideas for how pharmacies could be used to help deliver on the key ambitions of the NHS – including case-finding and medication reviews – and we will continue to work together to make the case for those and to explore how they can be implemented.

“Community pharmacies ensure that millions of patients safely receive the medicines they need, when they need them. But we know that for community pharmacy to make a real contribution to this plan, we will need to see transformative change in the sector, shifting our funding from a focus on the dispensing of medicines to patient care and freeing up pharmacists’ time to offer more clinical services to patients.”

Source: https://psnc.org.uk
**PRODUCT INFORMATION**

**Accord Healthcare launches Tacrolimus 0.1% Ointment 30g and 60g**

Accord Healthcare is delighted to announce the launch of Tacrolimus 0.1% Ointment 30g and 60g. This medicine is indicated in adults and adolescents (16 years of age and above) for flare treatment of moderate to severe atopic dermatitis in adult patients who are not adequately responsive to, or are intolerant of, conventional therapies such as topical corticosteroids. It is also indicated for maintenance treatment of moderate to severe atopic dermatitis in patients experiencing a high frequency of disease exacerbations. Please check the Summary of Product Characteristics (SPC) for full indications. The SPC is available at www.hpra.ie or for healthcare professionals at www.accord-healthcare.ie.

For further information, please contact Accord in Cork on 021 461 9040 or visit www.accord-healthcare.ie.

Product subject to prescription which may not be renewed (S1A).

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**NEW Bio-Oil® Dry Skin Gel from Bio-Oil®**

Ocean Healthcare is delighted to announce the launch of Bio-Oil® Dry Skin Gel this January – the first new product from Bio-Oil® since its launch 30 years ago. Bio-Oil® Dry Skin Gel’s formula breakthrough has pioneered a way to replace water with oil, making the product 100% active. Bio-Oil® Dry Skin Gel has substantially higher levels of oil, meaning that it’s better at forming a protective matrix on the skin to lock in moisture.

Bio-Oil® Dry Skin Gel has been clinically proven to significantly improve dry skin, with 82% of trial participants recording a difference in just two days. Two thirds of trial participants agreed that it is better than any product they have ever used before to combat dry skin and 96% of trial participants agreed that “a little goes a long way” and importantly, 83% agreed it absorbed easily into the skin.*

Bio-Oil® Dry Skin Gel will be supported with a heavyweight marketing campaign including national TV and radio throughout the year, extensive PR and a comprehensive digital marketing campaign. New point of sale and training material will also be available. Bio-Oil® Dry Skin Gel will be available from Ocean Healthcare and United Drug.

For more information, contact Ocean Healthcare 01 296 8080

*Split-body, evaluator-blinded, randomised and controlled trial
*Two-week trial on dry skin sufferers
National Standard on community-based ePrescribing published by HIQA

This National Standard defines the information requirements for the implementation of community-based ePrescribing and dispensing in Ireland. Information requirements are a minimum set of data items that are recommended for implementation in information systems, that create and transfer information, to support the delivery of safe and quality care to patients. The inclusion of data in the minimum set of data is determined by its clinical relevancy, and the potential for the data to improve patient safety in a collaborative care environment.

HIQA’s Director of Health Information and Standards, Rachel Flynn, said, “A national, community-based ePrescribing programme can deliver significant benefits for patients, prescribers and pharmacists. It can improve patient safety considerably by reducing cases of incorrect dosage, incorrect medication and adverse drug interactions. A national ePrescribing service can also benefit prescribers by enabling the safe electronic sharing of prescription information. Prescribers can receive notifications when a patient collects a prescription from a pharmacy. Electronic prescribing can improve the efficiency of processes within pharmacies, thus allowing pharmacists to give more time to patients.”

The Sláintecare Implementation Strategy, published in August 2018, prioritises the implementation of community-based ePrescribing to support information sharing, patient empowerment and the development of digital services.

The National Standard on information requirements for national community-based ePrescribing can be found on www.hiqa.ie

To mark the 12th annual World Rare Disease Day, Rare Diseases Ireland has announced details of its forthcoming conference Bridging Health & Social Care. Taking place on 28 February in Chartered Accountants House, Pearse Street, Dublin 2, the conference will highlight the importance of joined-up hospital, primary care and community services for people with rare diseases. Among the topics under discussion will be:

- Patient experiences of health and social care services;
- Best practices in delivering co-ordinated services to patients; and
- The current state of rare disease plans north and south.

Vicky McGrath, CEO of Rare Diseases Ireland, believes the conference will offer important insights in informing the development of a new national rare disease plan, “Ireland’s first national rare disease plan was for a period of five years and concluded on 31 December 2018 without a new plan to take its place. The focus of this year’s conference is on bridging health and social care and addressing the gaps between medical, social and support services. This conference offers a unique opportunity to inform Government and policy-makers of the importance of better connecting and co-ordinating our health and social care services for people with rare diseases and their families. The burden of rare diseases is enormous, and relatively simple steps, like co-ordinating care and social services, will go some way to help lighten this load.”

For more information on the work of Rare Diseases Ireland and to register for the forthcoming conference, visit www.rdi.ie/rdd-2019.
NUI Galway leads on cross-border health intervention on multiple medication review

NUI Galway is leading on a health intervention research trial involving people with more than one long-term medical condition, thanks to a new cross-border Healthcare Intervention Trials in Ireland Network (CHITIN).

A pilot cluster randomised controlled trial will involve general practitioners (GPs) and practice-based pharmacists from Northern Ireland and the Republic of Ireland to exploring a new approach to reviewing prescribing for patients with more than one long-term condition.

Currently, 5% of Irish patients aged over 65 are on 15 or more drugs. There are obvious concerns about being able to take these drugs reliably including potential side-effects. This study looks at a way of trying to improve the effectiveness and safety of their drug intake where two GPs, or a GP and a practice-based pharmacist, work together to find out the best possible combination of medicines for that patient.

The pilot trial aims to test this new approach to determine if it will lead to better patient care north and south of the border in Ireland. In helping to encourage people to be more involved in managing their own condition, eight GP practices in Northern Ireland and eight GP practices in the Republic of Ireland will participate in the trial.

If the pilot approach works, a larger trial will be undertaken to find out if it can make things better for patients.

For further details about the trial, contact Dr Nikita Burke at info@primarycaretrials.ie.
The Health Information and Quality Authority (HIQA) has published updated guidelines on the conduct of health technology assessment (HTA) in Ireland. The Guidelines for Evaluating the Clinical Effectiveness of Health Technologies in Ireland will assist decision-makers in evaluating the effectiveness of health technologies. Clinical effectiveness describes the ability of a technology to impact on a patient’s health.

The guidelines published are part of a suite of guidelines for health technology assessment. The updated clinical effectiveness guidelines outline the appropriate methods for evaluating the clinical effectiveness of health technologies. The guidelines are aimed at improving the accuracy and relevance of HTAs that are undertaken for the Irish healthcare system. The guidelines apply to assessments of all healthcare technologies including pharmaceuticals, procedures, medical devices, broader public health interventions and service delivery models.

Dr Conor Teljeur, HIQA’s Chief Scientist, said, “HIQA has developed these guidelines on the conduct of HTA in Ireland to ensure consistency in the HTAs undertaken by HIQA and others. The updated guidelines reflect changes to methodology and best practice. The guidelines are intended to promote the production of assessments that are timely, reliable, consistent and relevant to the needs of decision-makers and key stakeholders in Ireland. As health and social care services are publicly funded in Ireland, these guidelines promote the best use of limited public money and resources in ensuring the needs of the people using services are met.”

The guidelines are intended to be viewed as a complementary document to the Guidelines on Economic Evaluation of Health Technologies in Ireland and the Guidelines for Budget Impact Analysis of Health Technologies in Ireland.

The guidelines are available from www.hiqa.ie.

### Asthma Society survey: nearly half of people with asthma haven’t used a spacer device in the last year or ever

A recent survey conducted by the Asthma Society of Ireland on spacer device usage in Ireland, shows that 48% of people had not used a spacer device in the last year or never used one at all. The results of the survey also showed that outdated myths about asthma and spacer devices are still commonly believed by members of the public. Spacer devices should be used by children and adults every time they use their spacer-compatible inhaler device when prescribed by their doctor as a preferred medication delivery method.

The spacer device usage survey results show that:

- 41% of people with asthma do not use their spacer device regularly;
- One in five people surveyed believe spacer devices are for children only;
- 37% of people who have a child with asthma say their child does not have access to a spacer device in school;
- Only one in three people with asthma clean their spacer device as often as they should;
- 33% of people whose child has asthma said their child would feel very, or somewhat, embarrassed using their spacer device at school;
- 9% of people with asthma experience asthma attacks weekly; and
- 41% of people with asthma don’t visit their GP after an asthma attack.

The CEO of the Asthma Society of Ireland, Sarah O’Connor, said, “The results from the survey are very frightening to us. There is a huge gap in the public understanding of why they should use a spacer device and people are not getting optimal delivery of medication to their lungs as a result. 60% of people in Ireland have uncontrolled asthma and one person dies every week from asthma. A spacer device should be used every time a spacer-compatible inhaler is used, assuming the patient has been educated about how to use their spacer device. Spacer devices ensure the user gets the maximum benefit from their spacer-compatible asthma medication and helps direct it down into the lungs where it is needed. Spacer devices also decrease the risk of side-effects of using an inhaler alone and they are also more cost effective than using an inhaler by itself, as less medication is lost.”

For information on spacer devices and the Asthma Society’s Mystery of Spacers campaign, see www.asthma.ie.
RCSI research finds that older people are 72% more likely to have an inappropriate prescription after being hospitalised

A new study has found that older patients who were hospitalised were 72% more likely to be given a potentially inappropriate prescription after their hospital admission, independent of other patient factors. The study, conducted by the HRB Centre for Primary Care Research based in the Department of General Practice at RCSI (Royal College of Surgeons in Ireland), is published in the British Medical Journal. RCSI researchers looked at data from general practice records of 38,229 patients (aged ≥65 years) in Ireland from 2012 to 2015. To determine if the prescriptions were potentially inappropriate, they assessed the records using 45 criteria from the Screening Tool for Older Persons’ Prescription (STOPP) version 2.

Commenting on the findings, senior research fellow with the HRB Centre for Primary Care Research at RCSI, Dr Frank Moriarty, said, “Adults aged 65 years and older are a growing population and represent the largest consumers of prescribed medications. When caring for older patients in primary care, achieving the balance of maximising patients’ benefits from medicines while minimising harms and cost can be challenging. Research to date has focused on patient and GP characteristics as risk factors for poor prescribing quality. Our study illustrates the need to consider and address potential adverse effects of hospitalisation on prescribing appropriate medication for older patients.”

The study found that potentially inappropriate prescribing (PIP) is becoming increasingly prevalent in older people, and hospitalisation is independently associated with an increased risk of PIP. When compared to older people who had not been hospitalised in the past year, the probability of at least one PIP during a year increases by 49% for hospitalised patients after adjusting for other factors, such as the number of prescriptions and type of healthcare cover.

The research was conducted in collaboration with the Department of Statistics and Data Science, Complutense University of Madrid, with support from the Spanish Ministry of Economy, Industry and Competitiveness. The study was funded by the Health Research Board (HRB) in Ireland through the HRB Centre for Primary Care Research.


European Medicines Agency recommends fexinidazole, the first all-oral treatment for sleeping sickness

The European Medicines Agency’s Committee for Medicinal Products for Human Use (CHMP) has adopted a positive scientific opinion of fexinidazole, the first all-oral treatment that has been shown to be efficacious for both stages of sleeping sickness. This approval is a result of clinical trials led by the non-profit research and development organisation, DNDi, and an application submitted by Sanofi. The decision paves the way for the distribution of fexinidazole in endemic countries in 2019.

Fexinidazole is indicated as a 10-day once-a-day treatment for Trypanosoma brucei gambiensi sleeping sickness (the most common form of the disease, found in West and Central Africa). Importantly, fexinidazole is the first all-oral treatment that works both for (i) the early stage of the disease, as well as the (ii) second stage of the disease in which the parasites have crossed the blood-brain barrier, causing patients to suffer from neuropsychiatric symptoms.

In December 2017, Sanofi submitted a regulatory dossier to the European Medicines Agency under Article 58 of Regulation 726/2004, an innovative regulatory mechanism intended for the review of new medicines destined for use outside of the European Union. By allowing for the participation of endemic countries (DRC and Uganda) and of WHO in the evaluation of the fexinidazole regulatory dossier, approval under Article 58 also facilitates, and could accelerate, future national product registrations and patient access.

Medical exposure to ionising radiation to be regulated by HIQA

HIQA is now responsible for the regulation of medical exposure to ionising radiation. This follows the signing by the Minister for Health of a new Statutory Instrument governing the regulation of medical exposures to ionising radiation.

A medical exposure to ionising radiation is when a patient receives ionising radiation as part of their diagnosis or treatment. This could be an X-ray at a dentist, a CT scan at a hospital, a mammogram, or radiotherapy received as part of cancer treatment. It also includes exposure to radiation for medical or biomedical research purposes as well as carers and comforters exposed to ionising radiation while attending a patient.

Phelim Quinn, HIQA CEO, said, “To ensure medical exposure to ionising radiation is managed safely, it is important that all the places in which a patient is likely to be exposed are regulated, whether the provider is public or private. The first step in the regulation of medical exposure to ionising radiation is for all organisations that carry out medical exposures to declare themselves to HIQA on, or before, 8 April 2019. This new legislation will be the first time that HIQA will regulate healthcare facilities in the private sector and have enforcement powers to ensure compliance with these regulations in healthcare settings.”

Guidance on the regulation of medical exposure to ionising radiation is available at www.hiqa.ie.
FutureProofing Healthcare: The Sustainability Index launched

FutureProofing Healthcare: The Sustainability Index, was launched with the aim of starting an EU-wide conversation on the need to act now to futureproof healthcare systems in order to ensure patients will get the care they need in the coming decades.

The Index - which was led by an independent panel of healthcare experts from across the EU, in partnership with Roche – gives a unique snapshot of the current status of the 28 EU healthcare systems, based on the largest data set of its kind. It also includes a separate in-depth analysis of the state of care for breast cancer.

Ireland ranked eight out of 28 in the Sustainability Index with the indicators focused on Resilience and Quality driving the country’s highest score, while its lowest ranked vital sign was in Health Status1. Ireland is especially strong in training the next generation of healthcare professionals, while Irish people are the most likely to think they are in good health, compared to other EU countries1.

Meanwhile, the Breast Cancer Index found that Ireland had the highest score of the EU28 for palliative care, while ranking 13 out of 28 on the Breast Cancer Index overall1. The Index takes the form of a fully interactive, open source online dashboard, which can be accessed by anyone, from healthcare professionals and the media, to patients and members of the general public.

Speaking about the Index, Dr. Stephen Finn, Consultant Pathologist, St. James’s Hospital said, “The launch of this Index is extremely timely as it reinforces the need for action to be taken now to move the Irish healthcare system forward. Embracing innovation is crucial and structures must be put in place to enable us to do that, and manage the tsunami of information that improved technology will create, if we are to effectively futureproof our healthcare systems to ensure they are fit for purpose and fit for patients in the years ahead. That includes encouraging patients to take part in innovative studies and allowing them access to research and clinical trials to empower them to get the best care possible.”

Overall, the Index found that Northern European countries such as Sweden, Denmark, the Netherlands, Finland and Germany are currently leading the way with the most sustainable healthcare systems, but there are major regional disparities across the EU with Eastern European countries coming in at the lower end of the Index1. The Breast Cancer Index highlights a wide national variation on outcomes and survivorship across the EU281. Prevention and diagnosis scores well across many EU countries but there is a gap to close on standard of treatment1.

Healthcare sustainability is the effective use of our healthcare resources to ensure that we have sustainable resilient healthcare systems that can deliver care that patients need when they need it, now and into the future. Against a background of an ageing Europe and a rise in chronic illness, the need to make health systems sustainable by making them more effective, accessible and resilient has been recognised by policy makers at the EU and national level1.

The data is based on aggregates from over 2,400 data points on 83 individual healthcare measures from public sources such as the World Health Organisation (WHO) and the Organisation for Economic Co-Operation and Development (OECD), across 28 member states of the EU.

The data can be viewed by visiting www.FutureProofingHealthcare.com

References:
1. FutureProofing Healthcare: The Sustainability Index research was carried out by research group APCO Insight and is available at www.FutureProofingHealthcare.com. Full details of the methodology can be found on www.futureproofinghealthcare.com/our-methodology.
Boots Ireland and the Irish Cancer Society want to extend a very warm and grateful thank you to everyone who took part in the 2018 Boots Ireland Night Walks. Due to the incredible fundraising efforts of everyone involved, €50,000 was raised. Since the partnership began between Boots and the Irish Cancer Society in 2012, €1.4 million has now been raised for the Irish Cancer Society Night Nursing Service, the equivalent of over 4,064 nights of nursing care for families around the country.

Now in its 6th year, the Boots Night Walks for Night Nurses is designed to raise both funds and awareness of the critical care provided by the Irish Cancer Society Night Nurses. Over 500 people came together to take part in the two public walks in Dublin and Cork, and a further 38 regional walks were organised by Boots colleagues from stores across the country – making 2018 the biggest year yet for participation.

The Irish Cancer Society Night Nurses provide in-home care through the night for cancer patients requiring end-of-life care, whilst also providing rest and respite for the patient’s families. The service is provided free of charge and is an invaluable support to families and their loved ones during what can be a particularly difficult and anxious time. The service ensures patients and their loved ones receive nursing care, practical support and reassurance, keeping the patient comfortable and free of pain.

Bernadette Lavery, Managing Director, Boots Ireland, said, “Boots would like to extend a heartfelt thank you to everyone involved in making the 2018 Night Walks so special; your support really matters. The Night Nursing service is funded almost entirely by donations, so fundraising initiatives like the Night Walks are vital and make it possible for the Irish Cancer Society to reach people affected by cancer.”

For further information about the Irish Cancer Society Night Nursing service or to donate to the Irish Cancer Society, visit www.cancer.ie.

Boots Ireland Night Walks raises €50,000 for the Irish Cancer Society Night Nursing Service

CMRF Crumlin has announced research funding into premature babies. One baby in 16 is born prematurely in Ireland each year. These babies are admitted to neonatal units and often their families experience the stresses and difficulties arising from having their child admitted under neonatal care. CMRF Crumlin is funding two studies with the National Children’s Research Centre (NCRC), which aims to improve breathing support to premature newborns.

Dr Madeleine Murphy, who is part of the Clinical Research Fellowship in the NCRC and is working on completing her PhD, said, “The improvements that have been made in how we care for babies because of clinical research are huge. Currently, I’m involved in studying the care provided to ill and premature newborn babies, paying attention to the interventions they receive at birth and in the first few days of life. Research and infant participation in clinical trials has led to improved outcomes for babies.

“We’re conducting two studies right now. The first is called POPART (Prophylactic Oropharyngeal Surfactant for Preterm infants: A Randomised Trial). We are studying surfactant, a drug that is commonly given directly into the trachea (or windpipe) of premature babies who have immature lungs to help expand their lungs. Surfactant is a naturally produced substance, which is important for the development of the lungs in all babies, but especially in premature babies. Our study will show whether or not giving surfactant into the mouth of premature babies immediately after birth, so they can breathe it in, will prevent them from being ventilated for inadequate breathing. We will be extending the POPART trial across European centres in the coming months. The aim is to deliver surfactant in a less invasive way and avoid the negative effects of intubation and ventilation.

“The second study is called NEDI3 (estimating the insertion depth of neonatal endotracheal tubes using weight or suprasternal palpation of the tip). We are looking at intubation itself and how best to ensure the tube is in the correct position, should intubation be necessary. Using a simple feeling technique may result in more tubes being placed correctly. The standard way we estimate the depth of tube position is using the baby’s weight. However, this often results in misplaced tubes with less than optimal breathing support. If this technique proves more accurate, it may improve the ways we deliver breathing support to babies.

“We hope that these studies of the interventions received by premature and ill newborns in the first days of life will help us understand more about newborns at this vulnerable stage and translate in improvements in outcomes for babies worldwide.”

CMRF Crumlin is proud to fund this fellowship through the NCRC.
Minister Harris welcomes EU approval for new treatment option for patients with cystic fibrosis

Minister for Health Simon Harris T.D., has welcomed the announcement by Vertex Pharmaceuticals that it has received EU market authorisation for Symkevi. The decision will result in Irish patients having access to this important drug.

Minister Harris said, “I am delighted to see that a new treatment has been approved for CF patients in Ireland and their families. Over the next number of weeks, the HSE will work with Vertex to ensure timely access to this new treatment for Irish patients. This is a really important development and a significant day for patients with cystic fibrosis.”

Symkevi can assist with the treatment of people with cystic fibrosis aged 12 and older who either have two copies of the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene, or one copy of the F508del mutation and a copy of one of 14 mutations that result in residual CFTR activity. It is the first medicine in the EU to treat the CFTR protein defect in patients.

HPRA: Help make medicines safer by reporting suspected side-effects

The Health Products Regulatory Authority (HPRA) has taken part in the third annual social media campaign to promote the importance of reporting suspected side-effects from medicines. The campaign formed part of an awareness week involving 32 medicines regulators in the EU, Latin America, Australasia and the Middle East. Regulators will jointly focus on raising reporting numbers for suspected side-effects with an additional emphasis this year on the safe use of medicines in infants and children, and during pregnancy, including when breastfeeding.

While many people do not experience any problems when using medicines, side effects can happen, even with over-the-counter products. It is important the risks associated with all medicines are understood and communicated to healthcare professionals and their patients, including parents and carers, people planning for or expecting a baby. Potential side-effects may range from a headache or stomach ache, to flu-like symptoms or just ‘feeling a bit off’, and reporting these can help medicines regulators monitor the safe use of medicines on the market. In addition, reporting can help regulators to identify safety signals and, if necessary, to take action as appropriate to prevent future harm.

Regulators, such as the HPRA, rely on the reporting of suspected side-effects to make sure medicines on the market are acceptably safe. It is generally accepted however, that there is under-reporting of suspected side-effects – this is why the campaign is important to both raise awareness and help strengthen the system.

According to Dr Almath Spooner, Pharmacovigilance and Risk Management Lead at the HPRA, “The most important part of our work is making sure the medicines you and your family take are effective and acceptably safe. Our campaign will help raise awareness with parents and carers, including expectant mothers and those planning to have a baby. It’s important for them and healthcare professionals to report potential side-effects and have confidence their reports are making a difference. Everyone can help make medicines safer by reporting any suspected side-effects easily and quickly through our online report form which can be accessed on our website, www.hpra.ie.”
Medicines for Ireland made the call as the Charles Rivers Associates study*, published by the European Commission, found that proposed reforms to EU medicine regulations would result in savings for national health budgets of over €3 billion and create up to 25,000 additional direct high-skilled jobs.

Medicines for Ireland, the representative body for the generic, biosimilar and value-added medicines industry in Ireland, said that patients and the local economy risk losing-out on these potential gains unless the Government adopts a stronger stance in supporting the reforms.

Under the current rules, when a pharmaceutical company creates a new medicine, its molecule is typically protected by both a 20-year patent and a Supplementary Protection Certificate’, or SPC, which allows it to extend its market protection by up to an additional five years. Now the European Commission, as part of its ongoing strategy to make the EU more economically competitive on the global market, has proposed an SPC manufacturing waiver, which would allow generic manufacturers to produce drugs for export to territories where the SPC does not apply during the five-year period. The move would see more affordable medicines entering the market sooner, stimulating increased pharmaceutical manufacturing within the EU, thereby creating job creation opportunities in the process.

Medicines for Ireland is also calling on the Irish Government to improve the reforms further by supporting its day-1 launch proposal. This would allow EU patient-use of more affordable generic medicines immediately upon SPC expiry, rather than just the commencement of the manufacturing process as is currently the case. Under current regulations, EU pharmaceutical companies can only begin manufacturing the medicine after SPC expiry, yet similar generic medicines manufactured outside of the EU are available for patients use upon SPC expiry.

Commenting, Medicines for Ireland Chairperson and Mylan Country Manager, Owen McKeon, said, “The SPC waiver is a very positive proposal for the EU and Ireland in particular. It will deliver more affordable medicines, resulting in savings for both patients and the national health budget. It guarantees the intellectual property rights of pharmaceutical companies while simultaneously opening up international markets to generics manufacturers. If implemented, it offers the potential to create tens of thousands of highly skilled new jobs in Ireland’s pharma sector.”

*Charles Rivers Associates Study

- Net additional sales for the EU-based pharmaceutical industry of €7.3 to €9.5 billion by 2025;
- 20,000 to 25,000 additional direct jobs in Europe by 2025;
- Faster entry of generic and biosimilar competition in EU after SPC expiry – thus, better access for patients;
- Savings in pharmaceutical expenditures of up to €3.1 billion;
- Additional EU APIs sales of €211.8 to €254.3 million by 2030; and
- Additional 2,000 EU API-related jobs by 2030.

NEPHSTROM, which includes 12 academic, clinical and commercial partners from Ireland, Germany, the Netherlands, Belgium, Italy and the UK, is carrying out a randomised, placebo-controlled clinical trial of a novel allogeneic stromal cell therapy to treat diabetic kidney disease. Diabetic kidney disease is the single leading cause of end-stage renal disease in the industrialised world, accounting for 40% of new cases of end-stage renal disease in the US and EU and has a five-year mortality rate of 39% – a rate comparable to many cancers.

The NEPHSTROM team is carrying out a first in man clinical trial of a novel stromal cell therapy called ORBCEL-M, for diabetic kidney disease. ORBCEL-M was discovered by Dr Stephen Elliman, Chief Scientific Officer at Orbsen Therapeutics, an NUI Galway spinout cell therapy company ORBCEL-M performed well in pre-clinical models as a therapy for diabetic kidney disease demonstrating significant improvements in kidney function and structure. The NEPHSTROM clinical trial represents a significant step towards preparing this therapy for clinical use.

The pan-European NEPHSTROM clinical trial is being led by the renowned nephrologist Professor Giuseppe Remuzzi at the Mario Negri Institute in Bergamo, Italy, with clinical trial recruitment sites in Italy, Ireland (HRB Clinical Research Facility, NUI Galway), and the UK (UHBFT, Birmingham and BHSCT, Belfast). The primary aim of the clinical trial is to establish the safety and efficacy of ORBCEL-M. The NEPHSTROM team of researchers also hope to show that important markers of diabetic kidney disease are improved, meaning that the therapy actually works, as well as being safe.

For further information about NEPHSTROM (EC Project code 634086), visit www.nephstrom.eu.
Irish Heart Foundation poll reveals huge support for ban on advertising unhealthy foods and drinks to children

Just over 7 in 10 Irish adults are in favour of an outright ban on the advertising and promotion of unhealthy food and drinks to children, amid concerns over their role in Ireland’s child obesity crisis, a new poll for the Irish Heart Foundation has revealed.

The Ipsos MRBI research was released at an event in Dublin to launch a new parents campaign group as part of the Irish Heart Foundation’s Stop Targeting Kids campaign.

The poll showed that 71% of respondents support a blanket ban on advertising of products such as sugary drinks, snack foods, chocolate bars and crisps to children under 16 with 26% against and don’t knows of 3%. It also found that 79% believe advertising is a very big or fairly big contributor to childhood obesity. Meanwhile, 89% rated childhood obesity a very big or fairly big concern in Ireland.

Tim Collins, CEO of the Irish Heart Foundation, said, “There is conclusive and long-standing proof of a causal link between junk food marketing to children and child obesity. We know junk food marketing to children is rampant, we know it is fuelling obesity, we know this is damaging children’s health and we know the State is not doing enough to tackle the problem and is failing in its duty of care to protect children’s health.”

The poll showed that just over one-third of respondents were aware of regulations relating to marketing of unhealthy food and drinks to children.

The Irish Heart Foundation’s Stop Targeting Kids campaign is seeking public support. A petition at www.irishheart.ie/stoptargetingkids calls for action by the Government to regulate digital marketing aimed at Irish children and to close gaping loopholes in broadcast restrictions, which means that children still see over 1,000 junk food and drinks ads on television every year.

RCSI launches nurse-led research centre to develop solutions to treating wounds and trauma

A new research centre, specialising in wound healing and tissue repair, has been launched by the Royal College of Surgeons in Ireland (RCSI). The Skin Wounds and Trauma (SWaT) Research Centre, led by the RCSI School of Nursing, will have a particular focus on pressure ulcer prevention and management.

Wound management is a significant issue in healthcare. Based on data published by the International Wound Journal and by the European Wound Management Association, almost 5% of the population is affected by a wound at any given time, and up to 6% of healthcare budgets are spent on the management of these often preventable wounds.

The nurse-led research centre will bridge connections between research training, leadership and healthcare policy development in order that the research outcomes can inform clinical decision-making.

Centre Director, Prof Zena Moore, formerly served as the President of the European Wound Management Association, the largest wound care organisation in the world. She was the first appointed clinical nurse specialist in tissue viability, pioneering the growth of this clinical speciality in Ireland. “The launch of this research centre marks an important step forward in encouraging partnerships that will develop better practices for wound and trauma care, ultimately saving lives. It is expected that by 2025, more than 20% of Europeans will be aged 65 years or over, with a particularly rapid increase in numbers of over-80s. The prevalence of wounds increases with ageing; therefore, it is reasonable to predict that the burden of global wound care will increase unless current prevention and management strategies are challenged,” said Prof Moore.
Ireland has highest rates of Cystic Fibrosis in the world but is leading with research

One in 19 people in Ireland are carriers of the Cystic Fibrosis gene. The SHIELD Cystic Fibrosis study is a wide-ranging long-term study into cystic fibrosis to benefit patients in Ireland and internationally. The study was set up in 2010 by Prof. Paul McNally and Dr Barry Linnane. It has been funded through CMRF Crumlin and the National Children’s Research Centre (NCRC) from its inception and now involves over 250 children who have attended Our Lady’s Children’s Hospital, Crumlin, Tallaght and Limerick.

“Survival in cystic fibrosis over the last 20 years has come a long way from when I was a medical student where the average predicted survival was 25 years,” said Professor Paul McNally. “Now it’s 41 years. That is a result of the combined efforts of hundreds of research teams all around the world. The SHIELD CF study is longitudinal in its nature where samples are taken from patients throughout their early childhood years and followed up until their late teens. Patients as young as one are involved in the SHIELD CF study and throughout the years they will have both their clinical and biological data bio-banked for future use and study.

“Bio-banking involves taking samples such as blood, urine, fluid, lining cells and swabs, cataloguing them and storing them at -80°C. What this means is that if we have a question now or in the future, it won’t require a new study because we have all the samples and information there already.”

In the last 20 years, survival rates have improved dramatically in patients diagnosed with CF, however, it still remains a life limiting condition. With the high level of research participation in Our Lady’s Children’s Hospital, Prof. McNally has seen a marked change in patient and parent optimism when it comes to treating and tackling CF. “There hasn’t been one patient in seven years who has declined to take part in a research study. Without research there is no progress in medicine. What we have is a basic science core, a clinical research core and a national network in Ireland. We collaborate with researchers from all around the world. The structure of SHIELD CF will allow it to bear fruit for a generation. Research projects like this result in new possibilities, improved quality of care, and longer life expectancy for children with CF.”

Minister Harris welcomes the passing of the Children’s Health Bill through the Oireachtas and early establishment of Children’s Health Ireland

The Minister for Health Simon Harris T.D., has welcomed the passing of the Children’s Health Bill 2018 through the Oireachtas. The Bill provides for the establishment of a single statutory entity, Children’s Health Ireland, to provide paediatric services and take over responsibility for the services currently provided by the existing three Dublin children’s hospitals: Our Lady’s Children’s Hospital, Crumlin; Temple Street Children’s University Hospital; and the paediatric services at Tallaght University Hospital.

In addition to providing secondary and tertiary paediatric healthcare services, the new entity will also be the lead centre for paediatric education, training, research and innovation in Ireland. It will also be the centre of a national clinical network for paediatric services.

Minister Harris said, “The establishment of this new body will, together staff and services from the three existing children’s hospitals into a single organisation in advance of the opening of the paediatric outpatients and urgent care centres at Connolly Hospital in 2019 and at Tallaght University Hospital in 2020, and the new children’s hospital in 2022. The Children’s Hospital Group Board will be the first Board of Children’s Health Ireland when it is established later this year with a view to taking over responsibility for the staff and services of the three children’s hospitals from the beginning of next year. As a body corporate established by an Act of the Oireachtas, Children’s Health Ireland will have the powers and functions it needs as the national tertiary paediatric service. It will also have the necessary status to take on a leadership role nationally, in relation to paediatric healthcare and as an international player in paediatric research and innovation.”
Two-thirds of people say patients’ wait for new medicines is ‘unacceptable’ – Ipsos MRBI Survey for IPHA

Two-thirds of people feel it is unacceptable that life-changing medicines are available to patients in other countries before our own can get them, according to a survey conducted by Ipsos MRBI on behalf of the Irish Pharmaceutical Healthcare Association (IPHA), the organisation that represents pharmaceutical innovators in Ireland. The results are part of a major new healthcare landscape survey by Ipsos MRBI for IPHA aimed at testing public attitudes to medical innovation and healthcare needs.

Ireland is an outlier in western Europe when it comes to the availability of new treatments, often coming last among other countries, even for some medicines that are made here. The most recent IPHA analysis of a batch of new treatments found that the average wait time is 792 days – two and a half times slower than other western European countries.

The Ipsos MRBI survey showed that 9 out of 10 people believe that Irish patients should have access to the same range of medicines as other western European countries. More than four in five people believed savings delivered by the industry should be reinvested into making new medicines available to patients. Almost 9 in 10 people agreed that it is important for the Government to continue supporting pharmaceutical innovation, according to the survey.

The survey showed the public expects pharmaceutical innovators to continue discovering and manufacturing new treatments, with the Government backing their efforts with the right public policy environment.

When asked to characterise their opinion of pharmaceutical companies, 44% of people said it was positive. More than half of that cohort cited innovation and human health impact as the reasons for their positive disposition towards the industry. Just 16% of people said their opinion about the industry was negative. Those who had a neutral opinion about the industry numbered 37%. The rest, 4%, said they didn’t know.

Oliver O’Connor, IPHA CEO, said, “As an industry, we must remain focused on what we can and should deliver for patients, in partnership with the Government. This should be our pledge to patients: that we will, together, deliver the best medical innovation for their care. The survey captures the expectations of the public that the best treatments be made available here as fast as other peer countries in Europe. If we are to invest in innovation, then it follows that we should make the medicines that emerge from that process available to patients quickly. That is the premise of the Manifesto for Better Health, the link between access and innovation.”

Irish Cancer Society wins first prize for outstanding initiatives on prevention of tobacco use in the EU

The Irish Cancer Society has won first prize of €20,000 in the EU Health Award for NGOs Working to Prevent Tobacco Use for their X-HALE Youth Smoking Prevention Programme. The prize was awarded for the innovative social dimension of their campaign, the peer-to-peer approach and tackling vulnerable groups.

The aim of the EU Health Award for NGOs Working to Prevent Tobacco Use is to reward outstanding initiatives by NGOs which have helped achieve higher levels of public health for Europeans, through actions aimed at avoiding tobacco use initiation among adolescents and young adults. Mr Vytenis Andriukaitis, the European Commissioner for Health and Food Safety, announced the winners of the 2018 awards.

Congratulating the Irish Cancer Society, Minister of State for Health Promotion and the National Drugs Strategy, Catherine Byrne T.D., said, “I am delighted that the Irish Cancer Society’s long running X-HALE programme has received justified recognition at EU level. The rates of smoking have declined in recent years and particularly amongst young people. Programmes like X-HALE and the advocacy work of the Irish Cancer Society generally has greatly assisted in this reduction. I would like to congratulate the Irish Cancer Society, the X-HALE programme leaders and, in particular, all the young participants for this tremendous achievement.”

For more information see www.ec.europa.eu.
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